

Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance
January 29, 2014
1:00 P.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Reimbursement Task Force- Murray Sheldon, CDRH-OCD

Guidance Development

- FDA issued 7 medical device guidance documents during the 1st quarter of FY 2014.
Barbara Zimmerman, CDRH-ODE; Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIR, Philip Desjardins, CDRH-OCD.

FDA MDUFA Performance — Actions through December 31, 2013

- Report on decisions goals for 1st quarter of FY 2014.
 - CDRH: *Barbara Zimmerman, CDRH.*
 - CBER: *Sheryl Kochman, CBER.*

Qualitative Update on Finances – 1st Quarter of FY 2014

- User fee receipts through the 1st quarter of FY 2014. *Lisa Berry, FDA-OFM.*

CDRH Registration and Listing

- Report on registration and listing- Dave Gartner, CDRH- OC.

Independent Assessment

- Progress and update- Amber Sligar, FDA-OC.

Discussion

- E-submission- Paul Fisher, CDRH-OCD

Set date for next meeting, following close of Q2. Target Date: Wednesday 4/30/14 at 10:00 am.

□□□

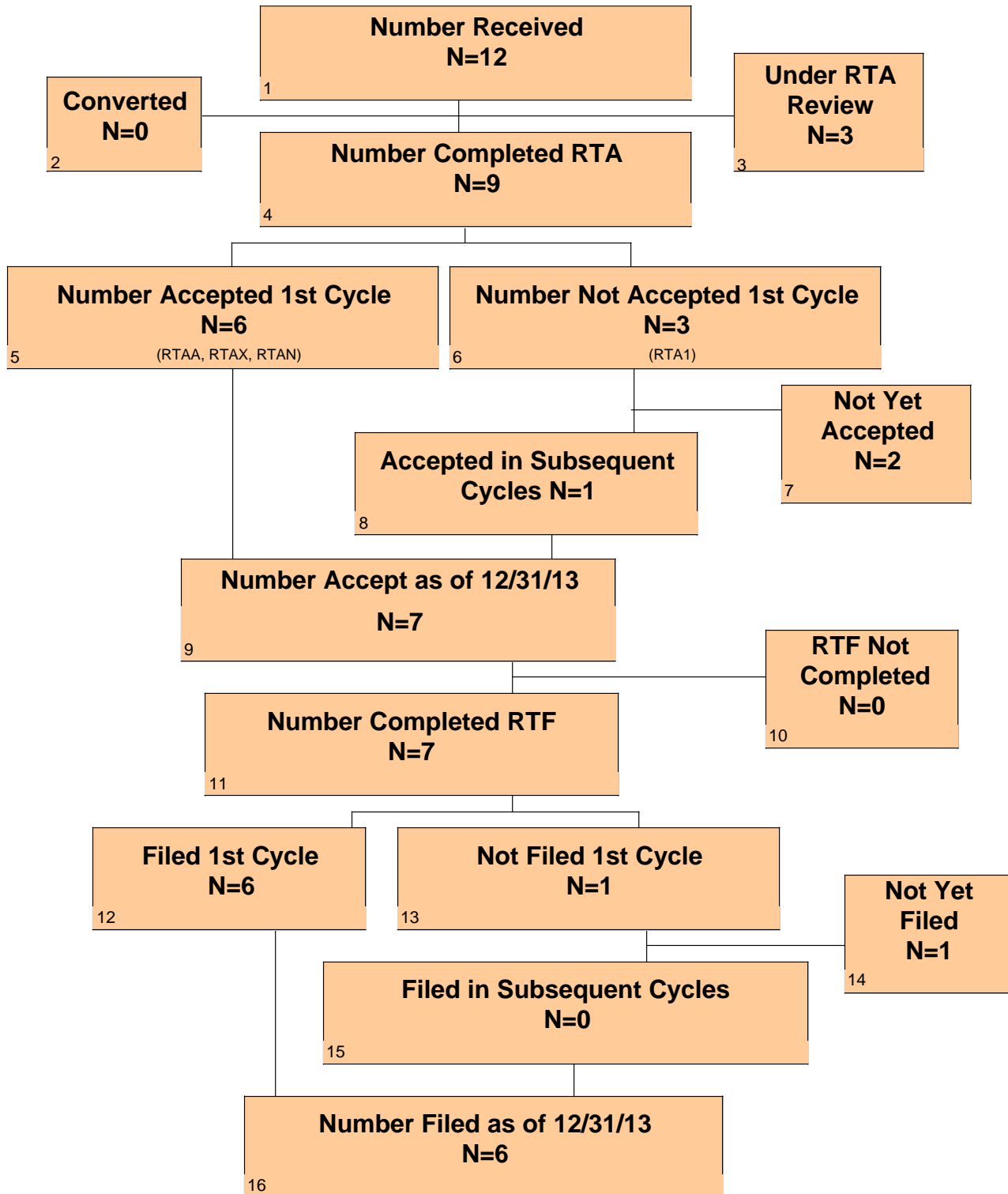
Medical Device Guidance Documents

Issued in FY 2014

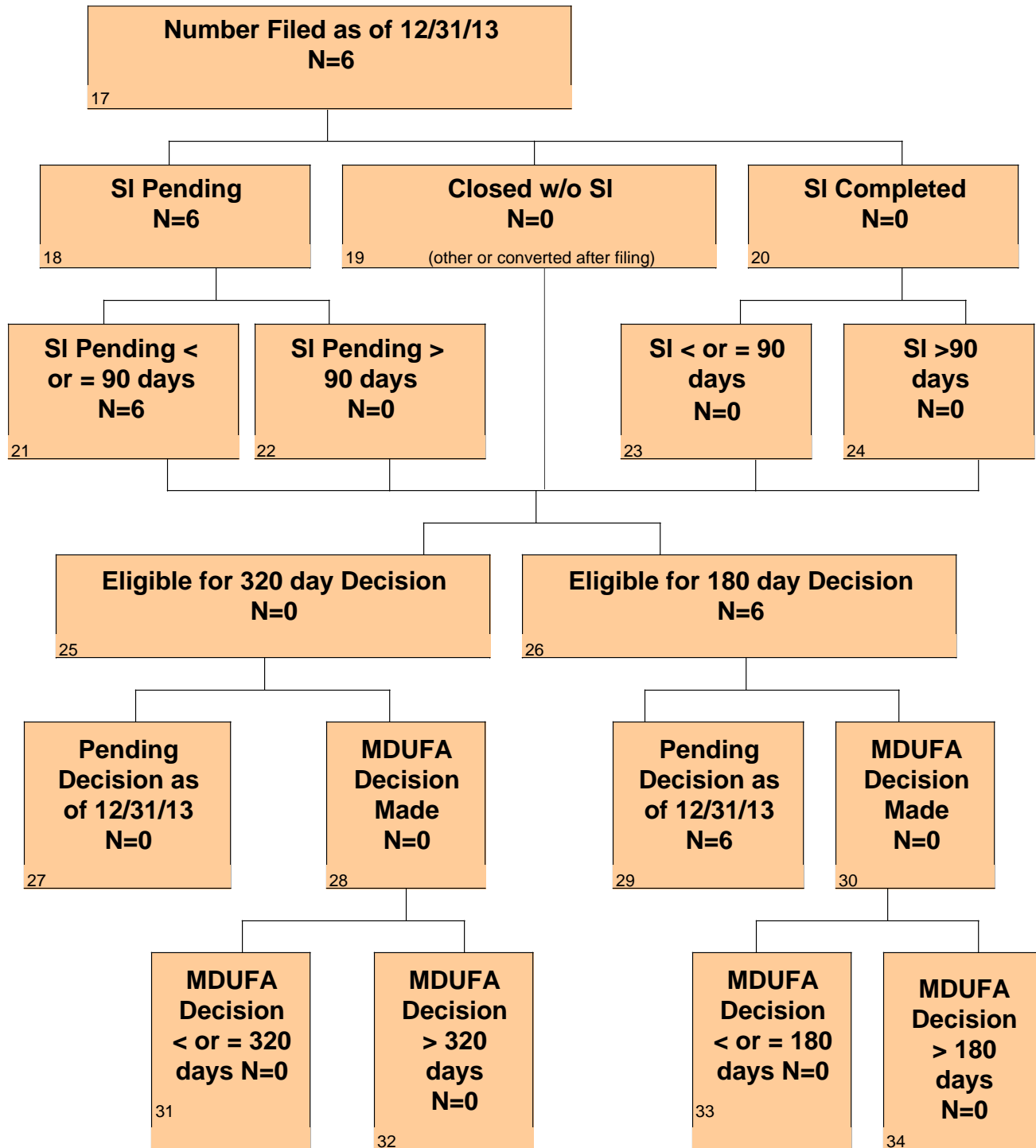
(October 1, 2012 thru December 31, 2013)

1. [Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate](#) (12/30/13)
2. [Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only - Guidance for Industry and Food and Drug Administration Staff](#) (11/25/13)
3. [Medical Device Development Tools - Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff](#) (11/14/13)
4. [Design Considerations for Pivotal Clinical Investigations for Medical Devices - Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff](#) (11/07/13)
5. [Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff](#) (11/07/13)
6. [Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions](#) (10/10/13)
7. [Investigational Device Exemptions \(IDEs\) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human \(FIH\) Studies - Guidance for Industry and Food and Drug Administration Staff](#) (10/01/13)

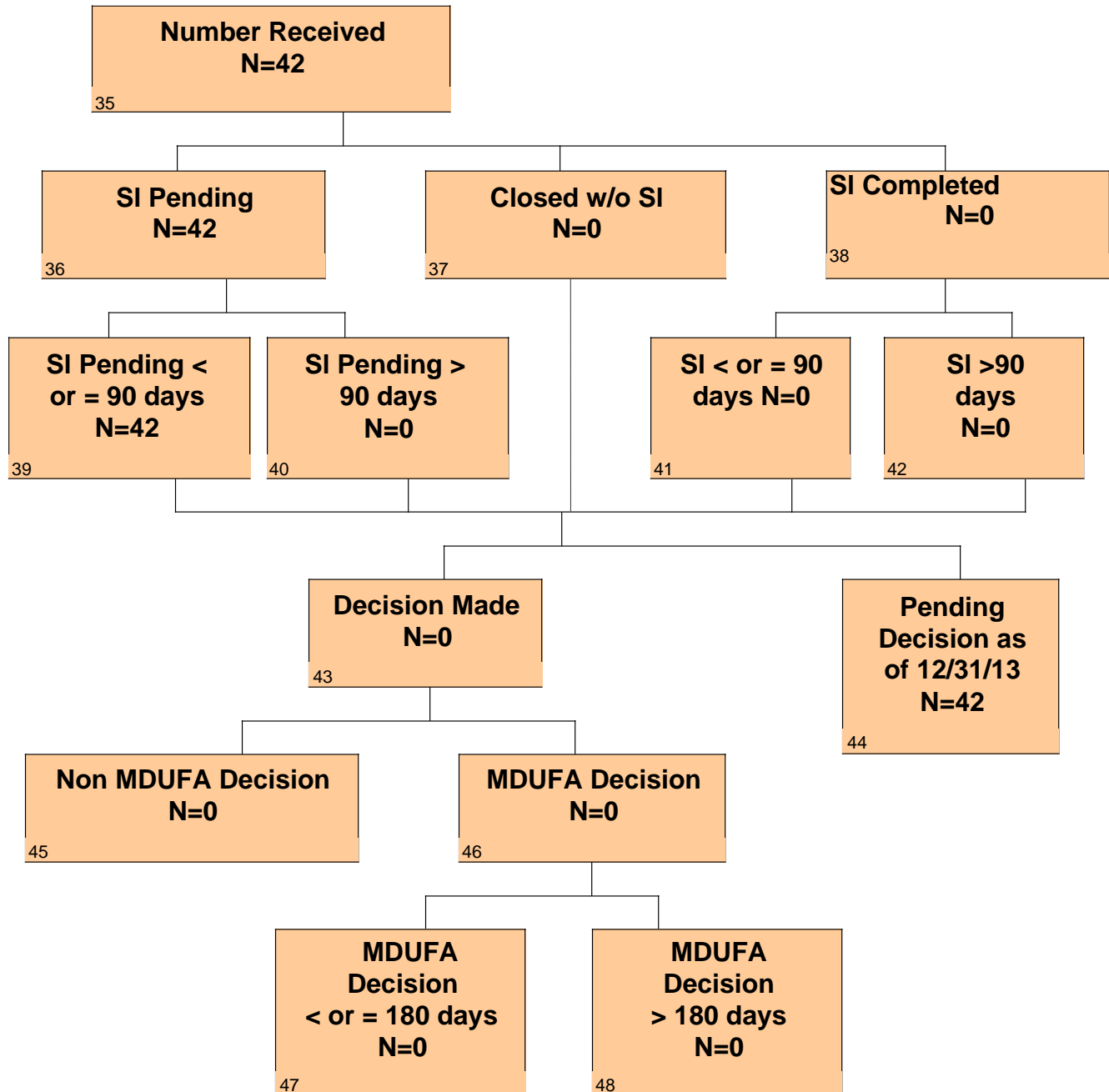
CDRH PMA Original and Panel Track Supplements - Received FY2014 (Decisions 10/01/13-12/31/13)



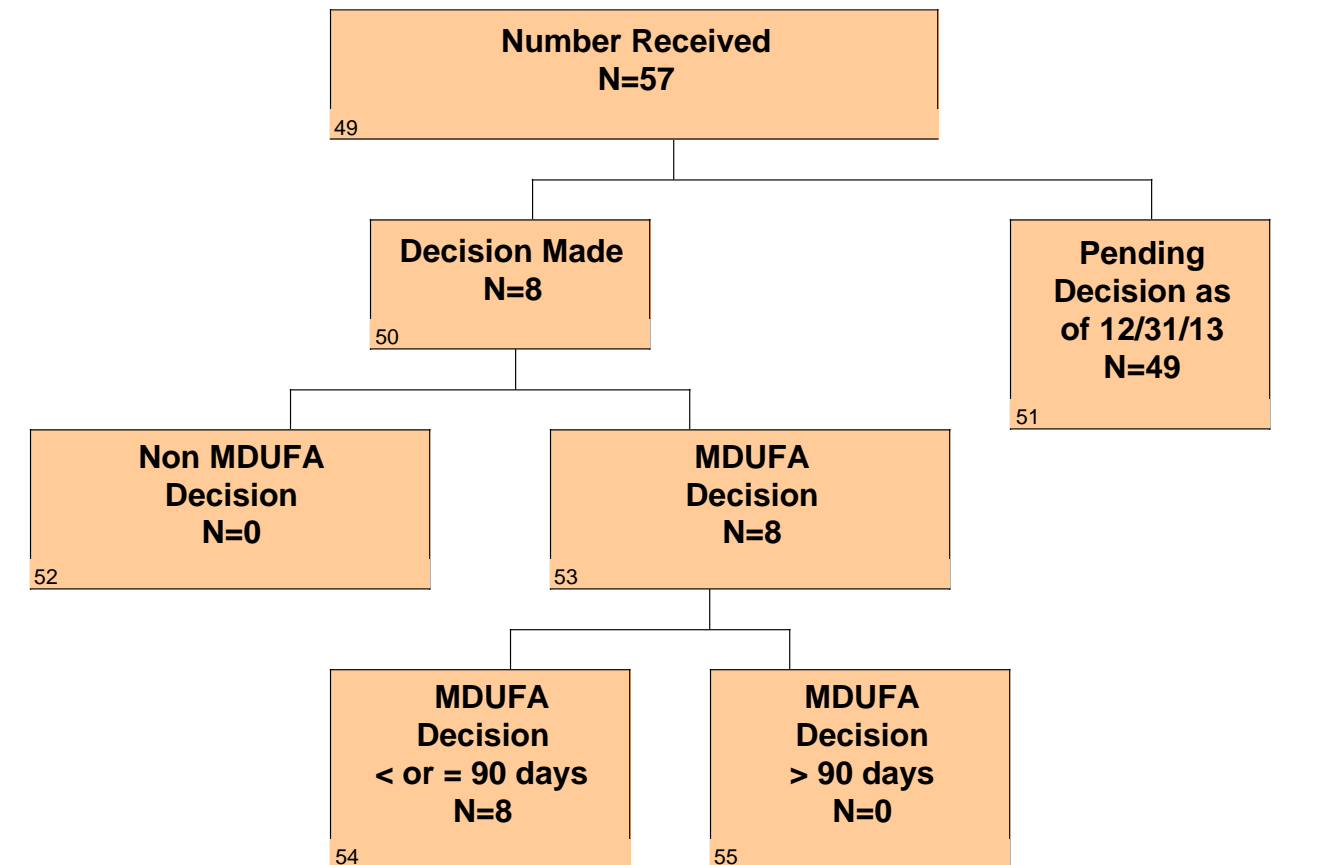
CDRH PMA Original and Panel Track Supplements - Received FY2014 (Decisions 10/01/13-12/31/13) Con't



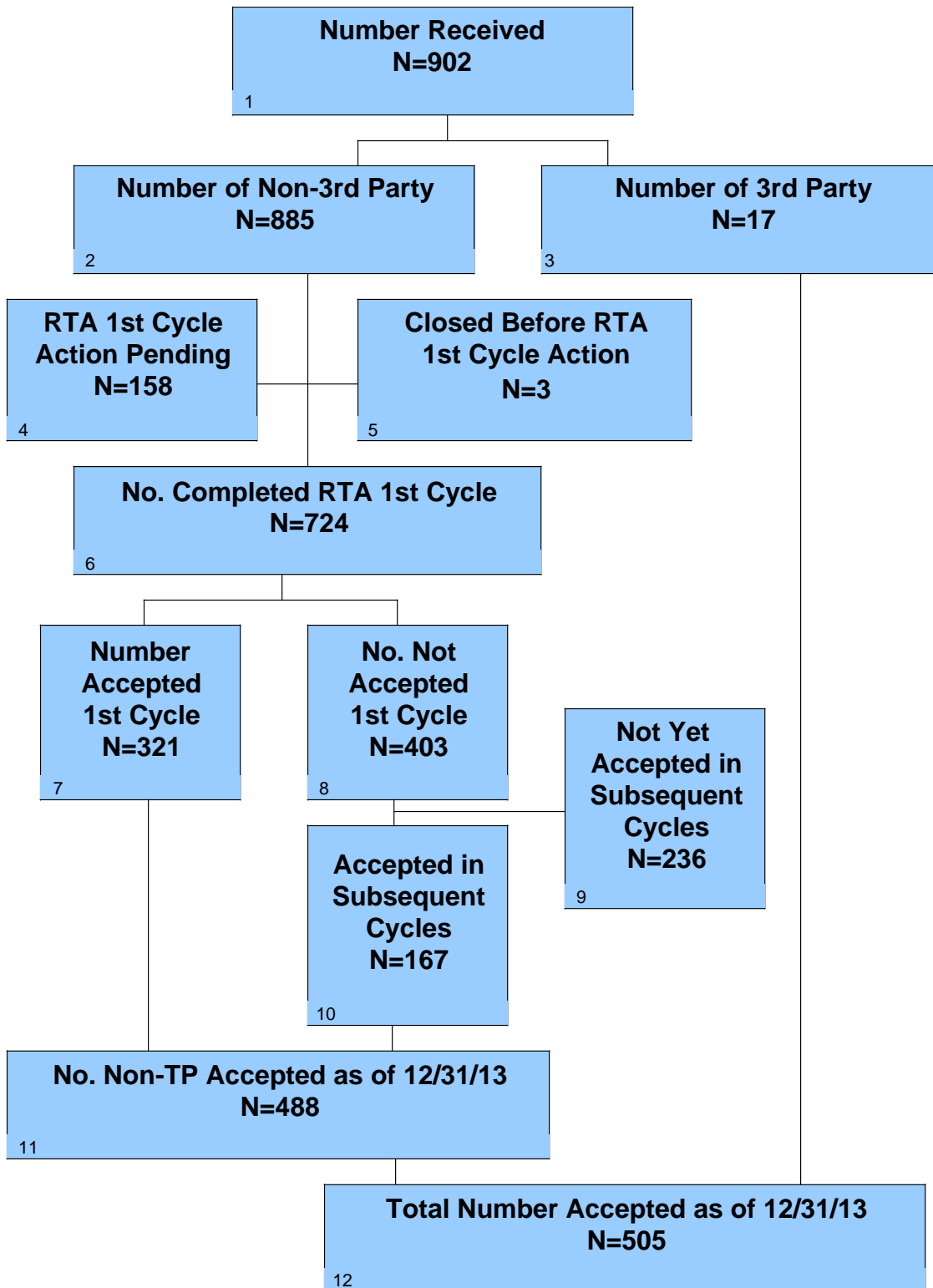
CDRH PMA 180 Day Supplements - Received FY2014 (Decisions 10/01/13-12/31/13)



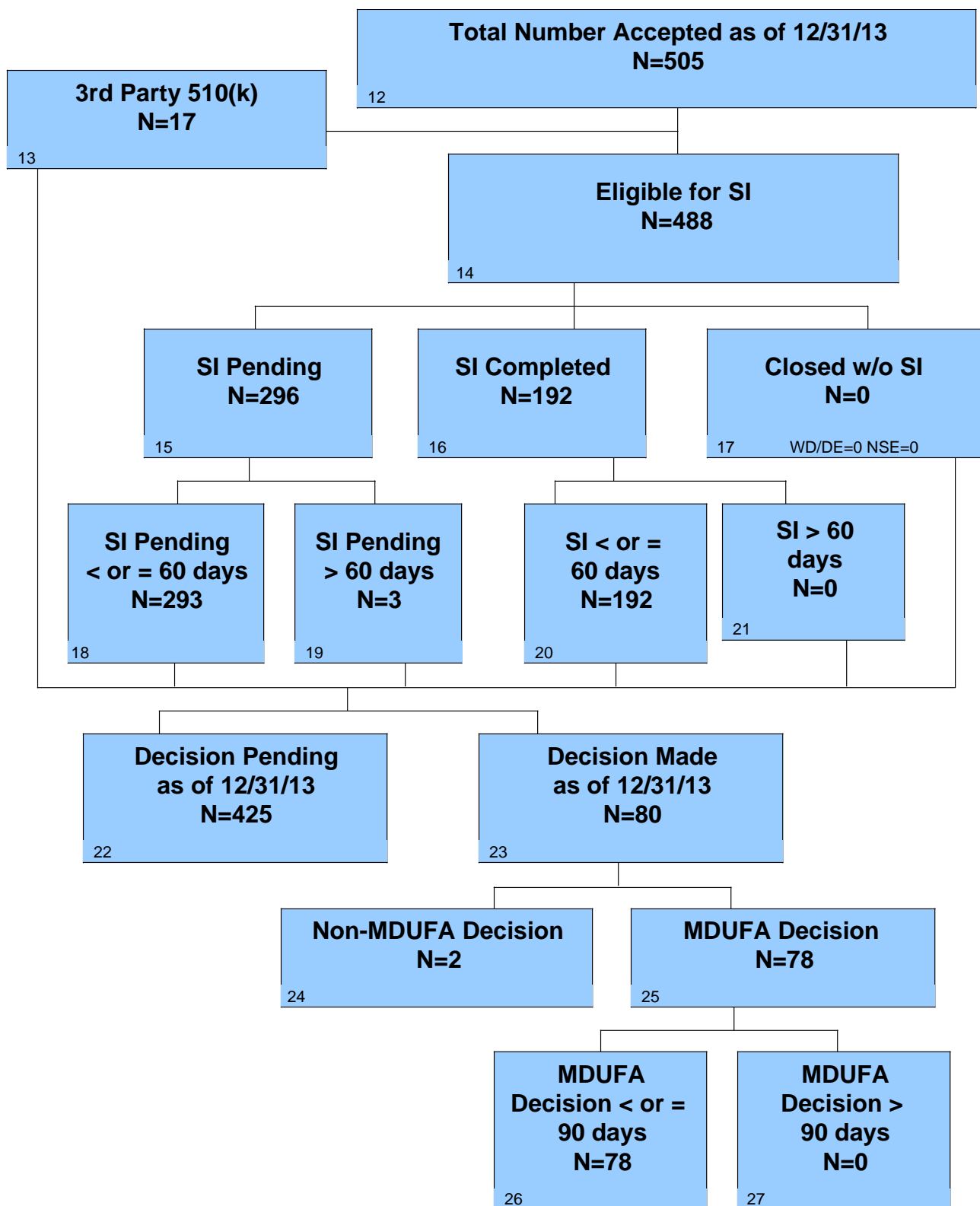
CDRH PMA Real Time Supplements - Received FY2014 (Decisions 10/01/13-12/31/13)



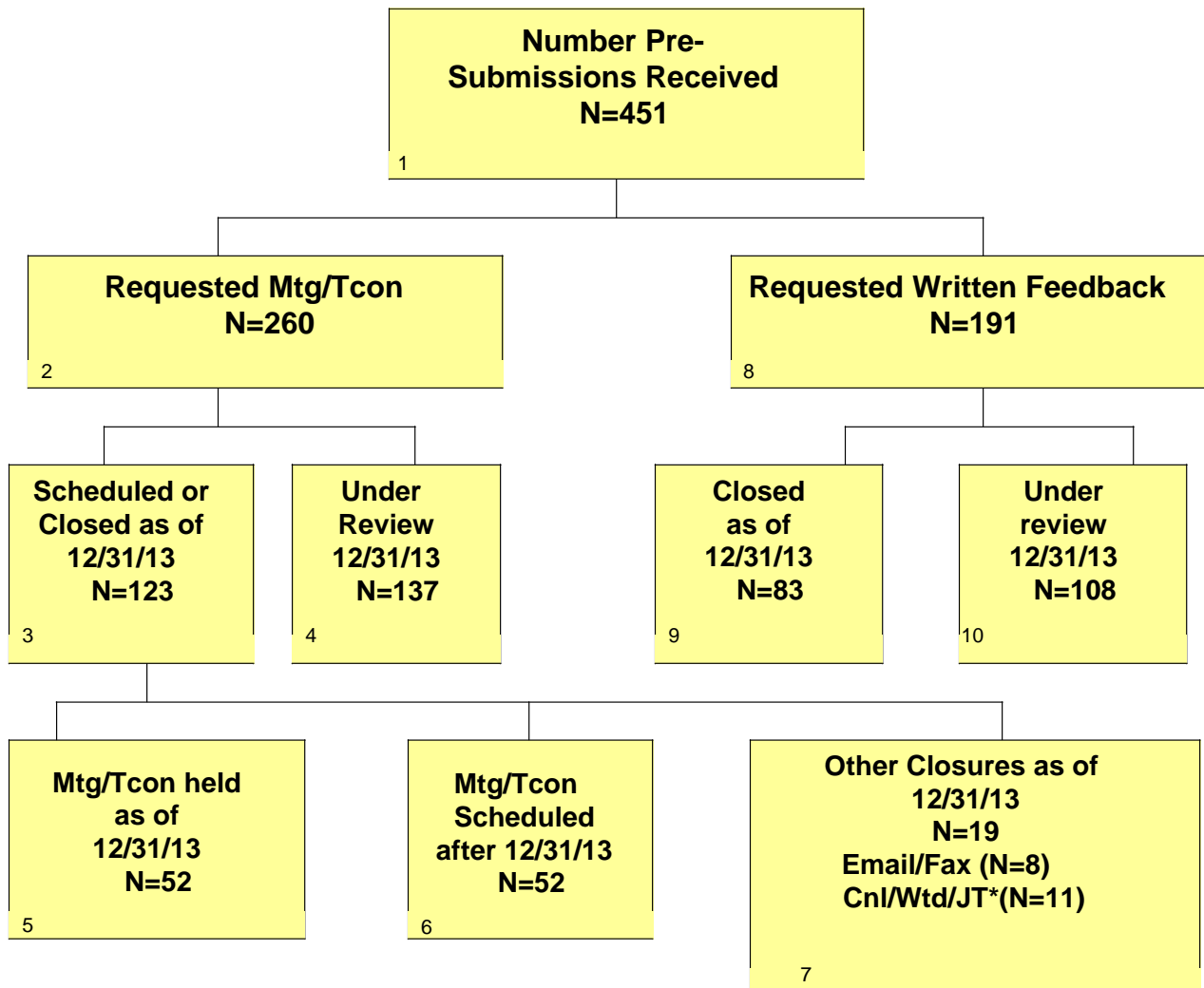
CDRH 510(k)s – Received FY2014 (Decisions 10/1/13 - 12/31/13)



CDRH 510(k)s – Received FY2014 (Decisions 10/1/13 - 12/31/13) Con't

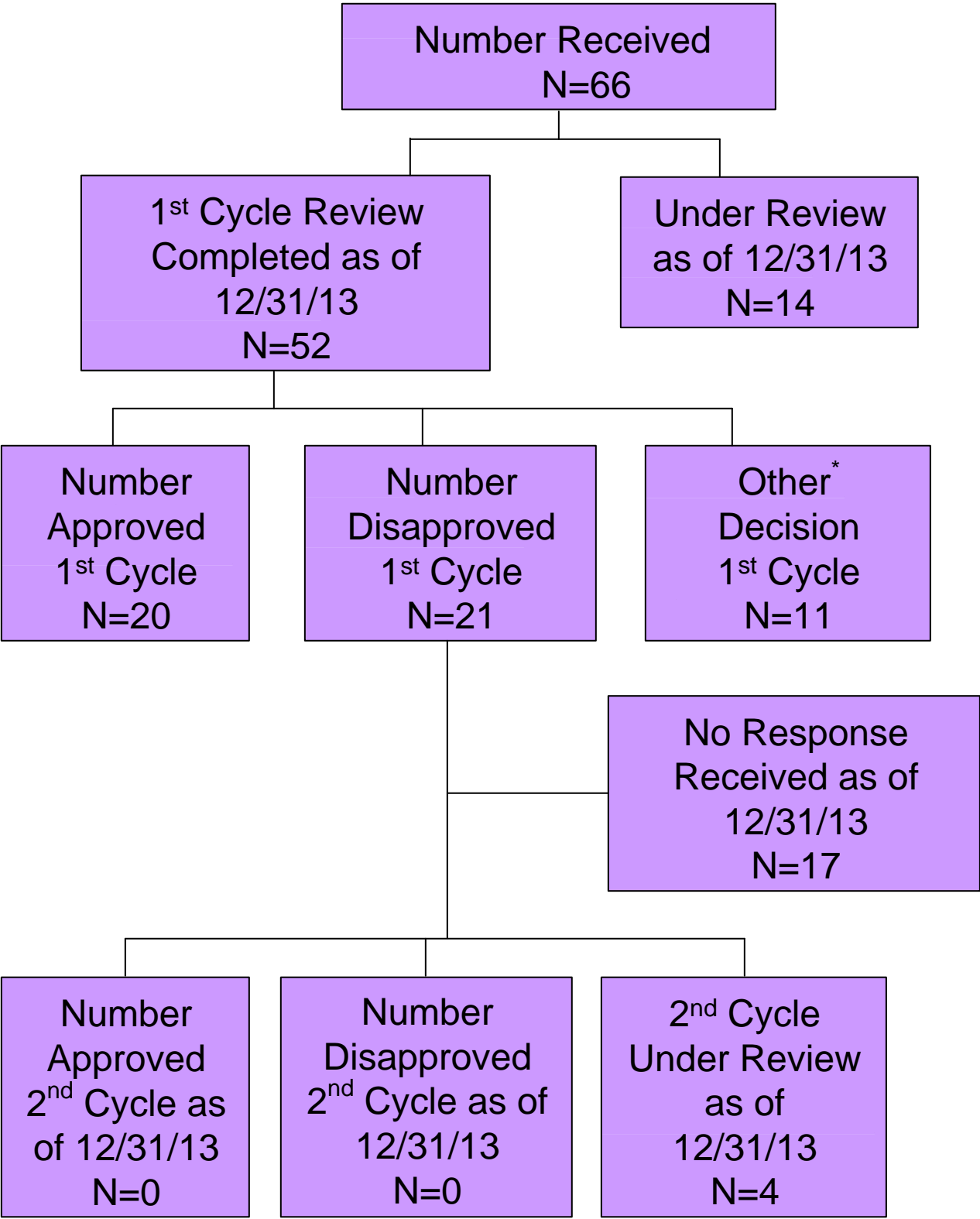


CDRH Pre-Submissions – Received FY2014 (Decisions 10/1/13 - 12/31/13)



*Cnl = Meeting/Tcon cancelled; Wtd = Submission Withdrawn; JT = Jurisdiction transferred

CDRH IDEs - Received FY2014 (Decisions 10/1/13 – 12/31/13)



*Other decisions include product jurisdiction transferred, nonsignificant risk device, RTA , or withdrawn

**Quarterly Update on
Medical Device Performance Goals
MDUFA III Performance Data**

October 1, 2012 – December 31, 2013

Report prepared by Ellen Pinnow and the MDUFA III Performance Goal Report Team

PMA

Wanda Sawyer-Major
Nicole Wolanski

510(k)

Margaret McCabe-Janicki
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Marjorie Shulman

Pre-Submission & IDE

Ellen Pinnow

CLIA Waiver/OIR

Jean Cooper
Elizabeth Hillebrenner

Edaptive Systems

Victor Kuttikattu
Jerry Logue
Arkady Soldatov
Steven Stone

Updated: 1/22/14

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Acronyms and Abbreviations

| | |
|--------|--|
| 510(k) | Premarket Notification |
| CDRH | Center for Devices and Radiologic Health |
| CLIA | Clinical Laboratory Improvement Act |
| DAGRID | Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices |
| DCD | Division of Cardiovascular Devices |
| DCTD | Division of Chemistry and Toxicology Devices |
| DIHD | Division of Immunology and Hematology Devices |
| DMD | Division of Microbiology Devices |
| DRH | Division of Radiological Health |
| DNPM | Division of Neurological and Physical Medicine Devices |
| DOD | Division of Orthopedic Devices |
| DOED | Division of Ophthalmic and Ear, Nose and Throat Devices |
| DRGUD | Division of Reproductive, Gastro-Renal, and Urological Devices |
| DSD | Division of Surgical Devices |
| IDE | Investigational Device Exemption |
| MDUFA | Medical Device User Fee Act |
| NSE | Not Substantially Equivalent |
| ODE | Office of Device Evaluation |
| OIR | Office of In Vitro Diagnostics and Radiological Health |
| PMA | Premarket Application |
| RTA | Refuse to Accept |
| RTF | Refuse to File |
| SE | Substantially Equivalent |
| SI | Substantive Interaction |

Note: Data may change in subsequent quarterly and annual reports.

Section 1 PMA Originals and Panel Track Supplements

PMA Originals and Panel Track Supplements – Center Level

Table 1.1 CDRH – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 34 | 12 | | | |
| Closed before RTA action | 1 | 0 | | | |
| Number with accepted RTA review | 26 | 6 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 1 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 3 | | | |
| Number Not Accepted for Filing Review | 6 | 3 | | | |
| Rate of submissions not accepted for filing review | 18% | 33% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1 for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2 CDRH – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 44 | 12 | | | |
| Number Accepted [#] | 37 | 6 | | | |
| Completed RTF | 43 | 7 | | | |
| Number Not Filed [@] | 3 | 1 | | | |
| Rate of submissions Not Filed | 7% | 14% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

Table 1.3 CDRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 42 | 6 | | | |
| SI within 90 FDA days | 40* | 0 | | | |
| SI over 90 FDA days | 2 | 0 | | | |
| SI pending within 90 FDA days | 0 | 6 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 95%* | N/A | | | |

* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

Table 1.4 CDRH – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 42 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 88 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| Maximum FDA days to Substantive Interaction | 117 | | | | |

Table 1.5 CDRH – PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 33 | 6 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 12 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 12 | 0 | | | |
| PMAs pending MDUFA III Decision | 21 | 6 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6 CDRH – PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 9 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 1 | 0 | | | |
| PMAs pending MDUFA III Decision | 8 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | 100% | N/A | | | |

**Table 1.7 CDRH – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 12 | 0 | | | |
| Average FDA days to MDUFA III decision | 159 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 128 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 176 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 179 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| Maximum FDA days to MDUFA III decision | 180 | | | | |
| Average Industry days to MDUFA III decision | 75 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 7 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 69 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 89 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 115 | | | | |
| Maximum Industry days to MDUFA III decision | 194 | | | | |
| Average Total days to MDUFA III decision | 234 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 180 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 198 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 236 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 277 | | | | |
| Maximum Total days to MDUFA III decision | 371 | | | | |

**Table 1.8 CDRH – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 1 | 0 | | | |
| Average FDA days to MDUFA III decision | 206 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| Maximum FDA days to MDUFA III decision | 206 | | | | |
| Average Industry days to MDUFA III decision | 0 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| Maximum Industry days to MDUFA III decision | 0 | | | | |
| Average Total days to MDUFA III decision | 206 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 206 | | | | |
| Maximum Total days to MDUFA III decision | 206 | | | | |

Table 1.9 CDRH – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 33 | 6 | | | |
| Number with MDUFA decision | 12 | 0 | | | |
| Number of Withdrawals | 1 | 0 | | | |
| Number of Not Approvable | 2 | 0 | | | |
| Rate of Withdrawals | 8% | N/A | | | |
| Rate of Not Approvable | 17% | N/A | | | |

Table 1.10 CDRH – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 9 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0.0% | N/A | | | |
| Rate of Not Approvable | 0.0% | N/A | | | |

**Table 1.11 CDRH – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

**Table 1.12 CDRH – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

PMA Originals and Panel Track Supplements – Office Level

Table 1.1.ODE ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 27 | 10 | | | |
| Closed before RTA action | 1 | 0 | | | |
| Number with accepted RTA review | 19 | 5 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 1 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 3 | | | |
| Number Not Accepted for Filing Review | 6 | 2 | | | |
| Rate of submissions not accepted for filing review | 23% | 29% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.ODE for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.ODE ODE – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 34 | 10 | | | |
| Number Accepted [#] | 27 | 5 | | | |
| Completed RTF | 33 | 6 | | | |
| Number Not Filed [@] | 3 | 1 | | | |
| Rate of submissions Not Filed | 9% | 17% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

Table 1.3.ODE ODE – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 32 | 5 | | | |
| SI within 90 FDA days | 30 | 0 | | | |
| SI over 90 FDA days | 2 | 0 | | | |
| SI pending within 90 FDA days | 0 | 5 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 94% | N/A | | | |

Table 1.4.ODE ODE – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 32 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 88 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 89 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| Maximum FDA days to Substantive Interaction | 117 | | | | |

Table 1.5.ODE ODE - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 26 | 5 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 9 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 9 | 0 | | | |
| PMAs pending MDUFA III Decision | 17 | 5 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6.ODE ODE – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 6 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 6 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.ODE ODE – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 9 | 0 | | | |
| Average FDA days to MDUFA III decision | 168 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 177 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 178 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| Maximum FDA days to MDUFA III decision | 180 | | | | |
| Average Industry days to MDUFA III decision | 61 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 36 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 72 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 99 | | | | |
| Maximum Industry days to MDUFA III decision | 194 | | | | |
| Average Total days to MDUFA III decision | 232 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 180 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 187 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 241 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 268 | | | | |
| Maximum Total days to MDUFA III decision | 371 | | | | |

Table 1.8.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.ODE ODE – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 26 | 5 | | | |
| Number with MDUFA decision | 9 | 0 | | | |
| Number of Withdrawals | 1 | 0 | | | |
| Number of Not Approvable | 2 | 0 | | | |
| Rate of Withdrawals | 11% | N/A | | | |
| Rate of Not Approvable | 22% | N/A | | | |

Table 1.10.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 6 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.ODE ODE – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.OIR OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 7 | 2 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 7 | 1 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 1 | | | |
| Rate of submissions not accepted for filing review | 0% | 50% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.OIR for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.OIR OIR – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 10 | 2 | | | |
| Number Accepted [#] | 10 | 1 | | | |
| Completed RTF | 10 | 1 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | 0% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.OIR OIR – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 10 | 1 | | | |
| SI within 90 FDA days | 10* | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 1 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100%* | N/A | | | |

* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

Table 1.4.OIR OIR – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 10 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 89 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 89 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| Maximum FDA days to Substantive Interaction | 112 | | | | |

**Table 1.5.OIR OIR - PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals**

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 7 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 3 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 3 | 0 | | | |
| PMAs pending MDUFA III Decision | 4 | 1 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

**Table 1.6.OIR OIR – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA
Decision Performance Goals**

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 3 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 1 | 0 | | | |
| PMAs pending MDUFA III Decision | 2 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | 100% | N/A | | | |

Table 1.7.OIR OIR – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 3 | 0 | | | |
| Average FDA days to MDUFA III decision | 130 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 106 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 113 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 128 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 151 | | | | |
| Maximum FDA days to MDUFA III decision | 174 | | | | |
| Average Industry days to MDUFA III decision | 107 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 90 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 109 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 121 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 127 | | | | |
| Maximum Industry days to MDUFA III decision | 133 | | | | |
| Average Total days to MDUFA III decision | 237 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 199 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 211 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 235 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 271 | | | | |
| Maximum Total days to MDUFA III decision | 307 | | | | |

Table 1.8.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 1 | 0 | | | |
| Average FDA days to MDUFA III decision | 206 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| Maximum FDA days to MDUFA III decision | 206 | | | | |
| Average Industry days to MDUFA III decision | 0 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| Maximum Industry days to MDUFA III decision | 0 | | | | |
| Average Total days to MDUFA III decision | 206 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 206 | | | | |
| Maximum Total days to MDUFA III decision | 206 | | | | |

Table 1.9.OIR OIR – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 7 | 1 | | | |
| Number with MDUFA decision | 3 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0% | N/A | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 1.10.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 3 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0.0% | N/A | | | |
| Rate of Not Approvable | 0.0% | N/A | | | |

Table 1.11.OIR OIR – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

PMA Originals and Panel Track Supplements – Division Level

Table 1.1.DAGRID DAGRID – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 1 | 0 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 0 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 1 | 0 | | | |
| Rate of submissions not accepted for filing review | 100% | N/A | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DAGRID for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DAGRID DAGRID – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 0 | | | |
| Number Accepted [#] | 1 | 0 | | | |
| Completed RTF | 2 | 0 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DAGRID DAGRID – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 2 | 0 | | | |
| SI within 90 FDA days | 2 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DAGRID DAGRID – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 85 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 84 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 85 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 85 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| Maximum FDA days to Substantive Interaction | 87 | | | | |

Table 1.5.DAGRID DAGRID - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 1.6.DAGRID DAGRID – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DAGRID DAGRID – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.8.DAGRID DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DAGRID DAGRID – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DAGRID DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DAGRID DAGRID – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DAGRID DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DCD DCD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 16 | 5 | | | |
| Closed before RTA action | 1 | 0 | | | |
| Number with accepted RTA review | 14 | 3 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 1 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 2 | | | |
| Number Not Accepted for Filing Review | 0 | 0 | | | |
| Rate of submissions not accepted for filing review | 0% | 0% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DCD DCD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 19 | 5 | | | |
| Number Accepted [#] | 18 | 3 | | | |
| Completed RTF | 18 | 3 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | 0% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DCD DCD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 18 | 3 | | | |
| SI within 90 FDA days | 17 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 3 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 94% | N/A | | | |

Table 1.4.DCD DCD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 18 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 88 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| Maximum FDA days to Substantive Interaction | 117 | | | | |

Table 1.5.DCD DCD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 15 | 3 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 7 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 7 | 0 | | | |
| PMAs pending MDUFA III Decision | 8 | 3 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6.DCD DCD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 3 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 3 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DCD DCD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 7 | 0 | | | |
| Average FDA days to MDUFA III decision | 165 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 176 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 178 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| Maximum FDA days to MDUFA III decision | 180 | | | | |
| Average Industry days to MDUFA III decision | 82 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 42 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 73 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 89 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 103 | | | | |
| Maximum Industry days to MDUFA III decision | 194 | | | | |
| Average Total days to MDUFA III decision | 248 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 187 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 228 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 255 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 277 | | | | |
| Maximum Total days to MDUFA III decision | 371 | | | | |

Table 1.8.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DCD DCD – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 15 | 3 | | | |
| Number with MDUFA decision | 7 | 0 | | | |
| Number of Withdrawals | 1 | 0 | | | |
| Number of Not Approvable | 2 | 0 | | | |
| Rate of Withdrawals | 14% | N/A | | | |
| Rate of Not Approvable | 29% | N/A | | | |

Table 1.10.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 3 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DCD DCD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DNPMD DNPMD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 1 | 2 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 0 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 1 | | | |
| Number Not Accepted for Filing Review | 1 | 1 | | | |
| Rate of submissions not accepted for filing review | 100% | 100% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2. DNPMD DNPMD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 1 | 2 | | | |
| Number Accepted [#] | 0 | 0 | | | |
| Completed RTF | 1 | 1 | | | |
| Number Not Filed | 0 | 1 | | | |
| Rate of submissions Not Filed | 0% | 100% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3. DNPMD DNPMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 1 | 0 | | | |
| SI within 90 FDA days | 0 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 0% | N/A | | | |

Table 1.4. DNPMD DNPMD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 1 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 92 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 92 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 92 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 92 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 92 | | | | |
| Maximum FDA days to Substantive Interaction | 92 | | | | |

Table 1.5. DNPMD DNPMD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 1 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6. DNPMD DNPMD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 0 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7. DNPMD DNPMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 1 | 0 | | | |
| Average FDA days to MDUFA III decision | 180 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 180 | | | | |
| Maximum FDA days to MDUFA III decision | 180 | | | | |
| Average Industry days to MDUFA III decision | 0 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| Maximum Industry days to MDUFA III decision | 0 | | | | |
| Average Total days to MDUFA III decision | 180 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 180 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 180 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 180 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 180 | | | | |
| Maximum Total days to MDUFA III decision | 180 | | | | |

Table 1.8. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9. DNPMD DNPMD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 0 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11. DNPMD DNPMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DOD DOD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 0 | 0 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 0 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 0 | | | |
| Rate of submissions not accepted for filing review | N/A | N/A | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DOD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DOD DOD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 0 | | | |
| Number Accepted [#] | 2 | 0 | | | |
| Completed RTF | 2 | 0 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DOD DOD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 2 | 0 | | | |
| SI within 90 FDA days | 2 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DOD DOD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 86 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| Maximum FDA days to Substantive Interaction | 86 | | | | |

Table 1.5.DOD DOD - PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 2 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 2 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 1.6.DOD DOD – PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 0 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DOD DOD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.8.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DOD DOD – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 2 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 0 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DOD DOD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DOED DOED – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 5 | 0 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 4 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 1 | 0 | | | |
| Rate of submissions not accepted for filing review | 20% | N/A | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DOED for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DOED DOED – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 6 | 0 | | | |
| Number Accepted [#] | 5 | 0 | | | |
| Completed RTF | 6 | 0 | | | |
| Number Not Filed [@] | 1 | 0 | | | |
| Rate of submissions Not Filed | 17% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

Table 1.3.DOED DOED – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 6 | 0 | | | |
| SI within 90 FDA days | 6 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DOED DOED – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 6 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 89 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 89 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| Maximum FDA days to Substantive Interaction | 90 | | | | |

Table 1.5.DOED DOED - PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 4 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 1 | 0 | | | |
| PMAs pending MDUFA III Decision | 3 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6.DOED DOED – PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 2 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 2 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DOED DOED – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 1 | 0 | | | |
| Average FDA days to MDUFA III decision | 177 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 177 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 177 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 177 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 177 | | | | |
| Maximum FDA days to MDUFA III decision | 177 | | | | |
| Average Industry days to MDUFA III decision | 0 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| Maximum Industry days to MDUFA III decision | 0 | | | | |
| Average Total days to MDUFA III decision | 177 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 177 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 177 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 177 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 177 | | | | |
| Maximum Total days to MDUFA III decision | 177 | | | | |

Table 1.8.DOE DOED – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DOE DOED – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 4 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0% | N/A | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 1.10.DOE DOED – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 2 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DOED DOED – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DOED DOED – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DRGUD DRGUD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 4 | 0 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 1 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 3 | 0 | | | |
| Rate of submissions not accepted for filing review | 75% | N/A | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DRGUD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DRGUD DRGUD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 4 | 0 | | | |
| Number Accepted [#] | 1 | 0 | | | |
| Completed RTF [@] | 4 | 0 | | | |
| Number Not Filed | 2 | 0 | | | |
| Rate of submissions Not Filed | 50% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

Table 1.3.DRGUD DRGUD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 3 | 0 | | | |
| SI within 90 FDA days | 3 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DRGUD DRGUD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 3 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 89 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 88 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 89 | | | | |
| Maximum FDA days to Substantive Interaction | 90 | | | | |

Table 1.5.DRGUD DRGUD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 3 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 3 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 1.6.DRGUD DRGUD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 0 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DRGUD DRGUD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.8.DRGUD DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DRGUD DRGUD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 3 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DRGUD DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 0 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DRGUD DRGUD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DRGUD DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DSD DSD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 0 | 3 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 0 | 2 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 1 | | | |
| Rate of submissions not accepted for filing review | N/A | 33% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DSD DSD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 0 | 3 | | | |
| Number Accepted [#] | 0 | 2 | | | |
| Completed RTF | 0 | 2 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | N/A | 0% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DSD DSD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 0 | 2 | | | |
| SI within 90 FDA days | 0 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 2 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | N/A | N/A | | | |

Table 1.4.DSD DSD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 0 | 0 | | | |
| Average number of FDA days to Substantive Interaction | | | | | |
| 20 th Percentile FDA days to Substantive Interaction | | | | | |
| 40 th Percentile FDA days to Substantive Interaction | | | | | |
| 60 th Percentile FDA days to Substantive Interaction | | | | | |
| 80 th Percentile FDA days to Substantive Interaction | | | | | |
| Maximum FDA days to Substantive Interaction | | | | | |

Table 1.5.DSD DSD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 0 | 2 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 2 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 1.6.DSD DSD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 0 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DSD DSD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.8.DSD DSD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DSD DSD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 2 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DSD DSD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DSD DSD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DSD DSD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DCTD DCTD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 2 | 0 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 2 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 0 | | | |
| Rate of submissions not accepted for filing review | 0% | N/A | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DCTD DCTD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 0 | | | |
| Number Accepted [#] | 2 | 0 | | | |
| Completed RTF | 2 | 0 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DCTD DCTD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 2 | 0 | | | |
| SI within 90 FDA days | 2 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DCTD DCTD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 90 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| Maximum FDA days to Substantive Interaction | 90 | | | | |

Table 1.5.DCTD DCTD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 2 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 1 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6.DCTD DCTD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 0 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DCTD DCTD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 1 | 0 | | | |
| Average FDA days to MDUFA III decision | 174 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 174 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 174 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 174 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 174 | | | | |
| Maximum FDA days to MDUFA III decision | 174 | | | | |
| Average Industry days to MDUFA III decision | 133 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 133 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 133 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 133 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 133 | | | | |
| Maximum Industry days to MDUFA III decision | 133 | | | | |
| Average Total days to MDUFA III decision | 307 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 307 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 307 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 307 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 307 | | | | |
| Maximum Total days to MDUFA III decision | 307 | | | | |

Table 1.8.DCTD DCTD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DCTD DCTD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 2 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DCTD DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DCTD DCTD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DCTD DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DIHD DIHD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 2 | 0 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 2 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 0 | | | |
| Rate of submissions not accepted for filing review | 0% | N/A | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DIHD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DIHD DIHD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 4 | 0 | | | |
| Number Accepted [#] | 4 | 0 | | | |
| Completed RTF | 4 | 0 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DIHD DIHD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 4 | 0 | | | |
| SI within 90 FDA days | 4* | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100%* | N/A | | | |

* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

Table 1.4.DIHD DIHD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 4 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 95 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 90 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 99 | | | | |
| Maximum FDA days to Substantive Interaction | 112 | | | | |

Table 1.5.DIHD DIHD - PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 3 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 2 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 2 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 1.6.DIHD DIHD – PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DIHD DIHD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 2 | 0 | | | |
| Average FDA days to MDUFA III decision | 108 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 102 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 106 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 109 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 113 | | | | |
| Maximum FDA days to MDUFA III decision | 116 | | | | |
| Average Industry days to MDUFA III decision | 95 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 80 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 90 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 99 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 109 | | | | |
| Maximum Industry days to MDUFA III decision | 118 | | | | |
| Average Total days to MDUFA III decision | 202 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 193 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 199 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 205 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 211 | | | | |
| Maximum Total days to MDUFA III decision | 217 | | | | |

Table 1.8.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DIHD DIHD – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 3 | 0 | | | |
| Number with MDUFA decision | 2 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0% | N/A | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 1.10.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11.DIHD DIHD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DMD DMD – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 2 | 1 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 2 | 1 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 0 | | | |
| Rate of submissions not accepted for filing review | 0% | 0% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DMD DMD – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 1 | | | |
| Number Accepted [#] | 2 | 1 | | | |
| Completed RTF | 2 | 1 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | 0% | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DMD DMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 2 | 1 | | | |
| SI within 90 FDA days | 2 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 1 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DRH DMD – DMD Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 86 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 86 | | | | |
| Maximum FDA days to Substantive Interaction | 86 | | | | |

Table 1.5.DMD DMD - PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 1 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 1.6.DMD DMD – PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | N/A | N/A | | | |

Table 1.7.DMD DMD – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.8.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.9.DMD DMD – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 1 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.11. DMD DMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.1.DRH DRH – PMA Original and Panel Track Supplements – Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 1 | 1 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number with accepted RTA review | 1 | 0 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 1 | | | |
| Rate of submissions not accepted for filing review | 0% | 100% | | | |

* RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

Table 1.2.DRH DRH – PMA Original and Panel Track Supplements – Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 1 | | | |
| Number Accepted [#] | 2 | 0 | | | |
| Completed RTF | 2 | 0 | | | |
| Number Not Filed | 0 | 0 | | | |
| Rate of submissions Not Filed | 0% | N/A | | | |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

Table 1.3.DRH DRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 2 | 0 | | | |
| SI within 90 FDA days | 2 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 1.4.DRH DRH – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 78 | | | | |
| 20 th Percentile FDA days to Substantive Interaction | 70 | | | | |
| 40 th Percentile FDA days to Substantive Interaction | 75 | | | | |
| 60 th Percentile FDA days to Substantive Interaction | 80 | | | | |
| 80 th Percentile FDA days to Substantive Interaction | 85 | | | | |
| Maximum FDA days to Substantive Interaction | 90 | | | | |

**Table 1.5.DRH DRH - PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals**

| Performance Goals: | FY 2013 70% within 180 FDA days | FY 2014 80% within 180 FDA days | FY 2015 80% within 180 FDA days | FY 2016 90% within 180 FDA days | FY 2017 90% within 180 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

**Table 1.6.DRH DRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA
Decision Performance Goals**

| Performance Goals: | FY 2013 50% within 320 FDA days | FY 2014 70% within 320 FDA days | FY 2015 80% within 320 FDA days | FY 2016 80% within 320 FDA days | FY 2017 90% within 320 FDA days |
|--|---|---|---|---|---|
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 1 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | 100% | N/A | | | |

Table 1.7.DRH DRH – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | | | | | |
| 20 th Percentile FDA days to MDUFA III decision | | | | | |
| 40 th Percentile FDA days to MDUFA III decision | | | | | |
| 60 th Percentile FDA days to MDUFA III decision | | | | | |
| 80 th Percentile FDA days to MDUFA III decision | | | | | |
| Maximum FDA days to MDUFA III decision | | | | | |
| Average Industry days to MDUFA III decision | | | | | |
| 20 th Percentile Industry days to MDUFA III decision | | | | | |
| 40 th Percentile Industry days to MDUFA III decision | | | | | |
| 60 th Percentile Industry days to MDUFA III decision | | | | | |
| 80 th Percentile Industry days to MDUFA III decision | | | | | |
| Maximum Industry days to MDUFA III decision | | | | | |
| Average Total days to MDUFA III decision | | | | | |
| 20 th Percentile Total days to MDUFA III decision | | | | | |
| 40 th Percentile Total days to MDUFA III decision | | | | | |
| 60 th Percentile Total days to MDUFA III decision | | | | | |
| 80 th Percentile Total days to MDUFA III decision | | | | | |
| Maximum Total days to MDUFA III decision | | | | | |

Table 1.8.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA decision | 1 | 0 | | | |
| Average FDA days to MDUFA III decision | 206 | | | | |
| 20 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 40 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 60 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| 80 th Percentile FDA days to MDUFA III decision | 206 | | | | |
| Maximum FDA days to MDUFA III decision | 206 | | | | |
| Average Industry days to MDUFA III decision | 0 | | | | |
| 20 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 60 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 80 th Percentile Industry days to MDUFA III decision | 0 | | | | |
| Maximum Industry days to MDUFA III decision | 0 | | | | |
| Average Total days to MDUFA III decision | 206 | | | | |
| 20 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 40 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 60 th Percentile Total days to MDUFA III decision | 206 | | | | |
| 80 th Percentile Total days to MDUFA III decision | 206 | | | | |
| Maximum Total days to MDUFA III decision | 206 | | | | |

Table 1.9.DRH DRH – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | N/A | N/A | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 1.10.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0.0% | N/A | | | |
| Rate of Not Approvable | 0.0% | N/A | | | |

Table 1.11.DRH DRH – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 1.12.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Section 2 PMA 180 Day Supplements

PMA 180 Day Supplements – Center Level

Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 182^ | 42 | | | |
| SI within 90 FDA days | 167 | 0 | | | |
| SI over 90 FDA days | 11 | 0 | | | |
| SI pending within 90 FDA days | 0 | 42 | | | |
| SI pending over 90 FDA days | 1 | 0 | | | |
| Closed without SI | 3^ | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 93% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.2 CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 182^ | 42 | | | |
| Non-MDUFA III Decisions | 4 | 0 | | | |
| MDUFA III Decisions | 128 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 127 | 0 | | | |
| Supplements pending MDUFA III Decision | 50 | 42 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 1 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 98% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.3 CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 182^ | 42 | | | |
| Number with MDUFA decision | 128 | 0 | | | |
| Number of Not Approvable | 6 | 0 | | | |
| Rate of Not Approvable | 5% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.4 CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 182 | | | | |
| Mean Industry days for submissions that missed goal | 0 | | | | |

PMA 180 Day Supplements – Office Level

Table 2.1.ODE ODE – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA Days | 85% SI within 90 FDA Days | 95% SI within 90 FDA Days | 95% SI within 90 FDA Days |
| Eligible for SI | 161^ | 39 | | | |
| SI within 90 FDA days | 146 | 0 | | | |
| SI over 90 FDA days | 11 | 0 | | | |
| SI pending within 90 FDA days | 0 | 39 | | | |
| SI pending over 90 FDA days | 1 | 0 | | | |
| Closed without SI | 3 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 92% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.2.ODE ODE – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 85% within 180 FDA days | 90% within 180 FDA days | 90% within 180 FDA days | 95% within 180 FDA days | 95% within 180 FDA days |
| Supplements received | 161^ | 39 | | | |
| Non-MDUFA III Decisions | 4 | 0 | | | |
| MDUFA III Decisions | 115 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 114 | 0 | | | |
| Supplements pending MDUFA III Decision | 42 | 39 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 1 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 98% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.3.ODE ODE – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 161^ | 39 | | | |
| Number with MDUFA decision | 115 | 0 | | | |
| Number of Not Approvable | 6 | 0 | | | |
| Rate of Not Approvable | 5% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.4.ODE ODE – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 182 | | | | |
| Mean Industry days for submissions that missed goal | 0 | | | | |

Table 2.1.OIR OIR – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 21 | 3 | | | |
| SI within 90 FDA days | 21 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 3 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 2.2.OIR OIR – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 21 | 3 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 13 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 13 | 0 | | | |
| Supplements pending MDUFA III Decision | 8 | 3 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.OIR OIR – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 21 | 3 | | | |
| Number with MDUFA decision | 13 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.OIR OIR – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

PMA 180 Day Supplements – Division Level

Table 2.1.DAGRID DAGRID – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 9 | 1 | | | |
| SI within 90 FDA days | 7 | 0 | | | |
| SI over 90 FDA days | 2 | 0 | | | |
| SI pending within 90 FDA days | 0 | 1 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 78% | N/A | | | |

Table 2.2.DAGRID DAGRID – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 9 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 4 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 4 | 0 | | | |
| Supplements pending MDUFA III Decision | 5 | 1 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DAGRID DAGRID – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 9 | 1 | | | |
| Number with MDUFA decision | 4 | 0 | | | |
| Number of Not Approvable | 1 | 0 | | | |
| Rate of Not Approvable | 25% | N/A | | | |

Table 2.4.DAGRID DAGRID – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DCD DCD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 115^ | 28 | | | |
| SI within 90 FDA days | 107 | 0 | | | |
| SI over 90 FDA days | 5 | 0 | | | |
| SI pending within 90 FDA days | 0 | 28 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 3 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 96% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.2.DCD DCD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 115^ | 28 | | | |
| Non-MDUFA III Decisions | 3 | 0 | | | |
| MDUFA III Decisions | 86 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 85 | 0 | | | |
| Supplements pending MDUFA III Decision | 26 | 28 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 99% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.3.DCD DCD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 115^ | 28 | | | |
| Number with MDUFA decision | 86 | 0 | | | |
| Number of Not Approvable | 4 | 0 | | | |
| Rate of Not Approvable | 5% | N/A | | | |

^ Includes one PMA 180 Day Supplement that was converted.

Table 2.4.DCD DCD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 182 | | | | |
| Mean Industry days for submissions that missed goal | 0 | | | | |

Table 2.1.DNPMD DNPMD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 8 | 3 | | | |
| SI within 90 FDA days | 7 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 3 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 88% | N/A | | | |

Table 2.2.DNPMD DNPMD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 8 | 3 | | | |
| Non-MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions | 6 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 6 | 0 | | | |
| Supplements pending MDUFA III Decision | 1 | 3 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DNPMD DNPMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 8 | 3 | | | |
| Number with MDUFA decision | 6 | 0 | | | |
| Number of Not Approvable | 1 | 0 | | | |
| Rate of Not Approvable | 17% | N/A | | | |

Table 2.4.DNPMD DNPMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DOD DOD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 2 | 0 | | | |
| SI within 90 FDA days | 2 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 2.2.DOD DOD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 2 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| Supplements pending MDUFA III Decision | 2 | 0 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 2.3.DOD DOD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | n/a | N/A | | | |

Table 2.4.DOD DOD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DOED DOED – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 12 | 5 | | | |
| SI within 90 FDA days | 11 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 5 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 92% | N/A | | | |

Table 2.2.DOED DOED – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 12 | 5 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 9 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 9 | 0 | | | |
| Supplements pending MDUFA III Decision | 3 | 5 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DOED DOED – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 12 | 5 | | | |
| Number with MDUFA decision | 9 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.DOED DOED – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DRGUD DRGUD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 10 | 2 | | | |
| SI within 90 FDA days | 9 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 2 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 90% | N/A | | | |

Table 2.2.DRGUD DRGUD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 10 | 2 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 8 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 8 | 0 | | | |
| Supplements pending MDUFA III Decision | 2 | 2 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DRGUD DRGUD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 10 | 2 | | | |
| Number with MDUFA decision | 8 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.DRGUD DRGUD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DSD DSD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 5 | 0 | | | |
| SI within 90 FDA days | 3 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 1 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 60% | N/A | | | |

Table 2.2.DSD DSD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 5 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 2 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 2 | 0 | | | |
| Supplements pending MDUFA III Decision | 3 | 0 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 1 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 67% | N/A | | | |

Table 2.3.DSD DSD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 5 | 0 | | | |
| Number with MDUFA decision | 2 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.DSD DSD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DCTD DCTD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 3 | 0 | | | |
| SI within 90 FDA days | 3 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 2.2.DCTD DCTD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 3 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| Supplements pending MDUFA III Decision | 3 | 0 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | N/A | N/A | | | |

Table 2.3.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 3 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | N/A | N/A | | | |

Table 2.4.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DIHD DIHD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 6 | 2 | | | |
| SI within 90 FDA days | 6 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 2 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 2.2.DIHD DIHD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 6 | 2 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 4 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 4 | 0 | | | |
| Supplements pending MDUFA III Decision | 2 | 2 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 6 | 2 | | | |
| Number with MDUFA decision | 4 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DMD DMD – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 7 | 0 | | | |
| SI within 90 FDA days | 7 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 2.2.DMD DMD – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 7 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 5 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 5 | 0 | | | |
| Supplements pending MDUFA III Decision | 2 | 0 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DMD DMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 7 | 0 | | | |
| Number with MDUFA decision | 5 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.DMD DMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 2.1.DRH DRH – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 90 FDA days | FY 2014 75% SI within 90 FDA Days | FY 2015 85% SI within 90 FDA Days | FY 2016 95% SI within 90 FDA Days | FY 2017 95% SI within 90 FDA Days |
|--|---|---|---|---|---|
| Eligible for SI | 5 | 1 | | | |
| SI within 90 FDA days | 5 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 1 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100% | N/A | | | |

Table 2.2.DRH DRH – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 85% within 180 FDA days | FY 2014 90% within 180 FDA days | FY 2015 90% within 180 FDA days | FY 2016 95% within 180 FDA days | FY 2017 95% within 180 FDA days |
|--|---|---|---|---|---|
| Supplements received | 5 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 4 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 4 | 0 | | | |
| Supplements pending MDUFA III Decision | 1 | 1 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100% | N/A | | | |

Table 2.3.DRH DRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 5 | 1 | | | |
| Number with MDUFA decision | 4 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 2.4.DRH DRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Section 3 PMA Real Time Supplements

PMA Real Time Supplements – Center Level

Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 305 | 57 | | | |
| Non-MDUFA III Decisions | 8 | 0 | | | |
| MDUFA III Decisions | 295 | 8 | | | |
| MDUFA III Decisions within 90 FDA Days | 294 | 8 | | | |
| Supplements pending MDUFA III Decision | 2 | 49 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 1 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 3.2 CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 305 | 57 | | | |
| Number with MDUFA decision | 295 | 8 | | | |
| Number of Not Approvable | 20 | 0 | | | |
| Rate of Not Approvable | 7% | 0% | | | |

Table 3.3 CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 97 | | | | |
| Mean Industry days for submissions that missed goal | 0 | | | | |

PMA Real Time Supplements – Office Level

Table 3.1.ODE ODE – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 266 | 42 | | | |
| Non-MDUFA III Decisions | 7 | 0 | | | |
| MDUFA III Decisions | 257 | 7 | | | |
| MDUFA III Decisions within 90 FDA Days | 256 | 7 | | | |
| Supplements pending MDUFA III Decision | 2 | 35 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 1 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 3.2.ODE ODE – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 266 | 42 | | | |
| Number with MDUFA decision | 257 | 7 | | | |
| Number of Not Approvable | 15 | 0 | | | |
| Rate of Not Approvable | 6% | 0% | | | |

**Table 3.3.ODE ODE – Real Time PMA Supplements Performance Metrics – Submissions
Missing Performance Goals**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 97 | | | | |
| Mean Industry days for submissions that missed goal | 0 | | | | |

Table 3.1.OIR OIR – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 39 | 15 | | | |
| Non-MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions | 38 | 1 | | | |
| MDUFA III Decisions within 90 FDA Days | 38 | 1 | | | |
| Supplements pending MDUFA III Decision | 0 | 14 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | 100% | | | |

Table 3.2.OIR OIR – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 39 | 15 | | | |
| Number with MDUFA decision | 38 | 1 | | | |
| Number of Not Approvable | 5 | 0 | | | |
| Rate of Not Approvable | 13% | 0% | | | |

Table 3.3.OIR OIR – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

PMA Real Time Supplements – Division Level

Table 3.1.DAGRID DAGRID – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 13 | 2 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 13 | 1 | | | |
| MDUFA III Decisions within 90 FDA Days | 13 | 1 | | | |
| Supplements pending MDUFA III Decision | 0 | 1 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | 100% | | | |

Table 3.2.DAGRID DAGRID – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 13 | 2 | | | |
| Number with MDUFA decision | 13 | 1 | | | |
| Number of Not Approvable | 1 | 0 | | | |
| Rate of Not Approvable | 8% | 0% | | | |

Table 3.3.DAGRID DAGRID – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DCD DCD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 174 | 27 | | | |
| Non-MDUFA III Decisions | 5 | 0 | | | |
| MDUFA III Decisions | 168 | 4 | | | |
| MDUFA III Decisions within 90 FDA Days | 168 | 4 | | | |
| Supplements pending MDUFA III Decision | 1 | 23 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | 100% | | | |

Table 3.2.DCD DCD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 174 | 27 | | | |
| Number with MDUFA decision | 168 | 4 | | | |
| Number of Not Approvable | 7 | 0 | | | |
| Rate of Not Approvable | 4% | 0% | | | |

Table 3.3.DCD DCD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DNPMD DNPMD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 23 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 23 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 23 | 0 | | | |
| Supplements pending MDUFA III Decision | 0 | 1 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | N/A | | | |

Table 3.2.DNPMD DNPMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 23 | 1 | | | |
| Number with MDUFA decision | 23 | 0 | | | |
| Number of Not Approvable | 1 | 0 | | | |
| Rate of Not Approvable | 4% | N/A | | | |

Table 3.3.DNPMD DNPMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DOD DOD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 8 | 5 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 8 | 2 | | | |
| MDUFA III Decisions within 90 FDA Days | 8 | 2 | | | |
| Supplements pending MDUFA III Decision | 0 | 3 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | 100% | | | |

Table 3.2.DOD DOD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 8 | 5 | | | |
| Number with MDUFA decision | 8 | 2 | | | |
| Number of Not Approvable | 2 | 0 | | | |
| Rate of Not Approvable | 25% | 0% | | | |

Table 3.3.DOD DOD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DOED DOED – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 16 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 16 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 16 | 0 | | | |
| Supplements pending MDUFA III Decision | 0 | 1 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | N/A | | | |

Table 3.2.DOED DOED – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 16 | 1 | | | |
| Number with MDUFA decision | 16 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 3.3.DOED DOED – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DRGUD DRGUD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 19 | 1 | | | |
| Non-MDUFA III Decisions | 2 | 0 | | | |
| MDUFA III Decisions | 17 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 17 | 0 | | | |
| Supplements pending MDUFA III Decision | 0 | 1 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | N/A | | | |

Table 3.2.DRGUD DRGUD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 19 | 1 | | | |
| Number with MDUFA decision | 17 | 0 | | | |
| Number of Not Approvable | 1 | 0 | | | |
| Rate of Not Approvable | 6% | N/A | | | |

Table 3.3.DRGUD DRGUD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DSD DSD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 13 | 5 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 12 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 11 | 0 | | | |
| Supplements pending MDUFA III Decision | 1 | 5 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 1 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 85% | N/A | | | |

Table 3.2.DSD DSD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 13 | 5 | | | |
| Number with MDUFA decision | 12 | 0 | | | |
| Number of Not Approvable | 3 | 0 | | | |
| Rate of Not Approvable | 25% | N/A | | | |

Table 3.3.DSD DSD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 97 | | | | |
| Mean Industry days for submissions that missed goal | 0 | | | | |

Table 3.1.DCTD DCTD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 6 | 7 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 6 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 6 | 0 | | | |
| Supplements pending MDUFA III Decision | 0 | 7 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | N/A | | | |

Table 3.2.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 6 | 7 | | | |
| Number with MDUFA decision | 6 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0% | N/A | | | |

Table 3.3.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DIHD DIHD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 20 | 7 | | | |
| Non-MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions | 19 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 19 | 0 | | | |
| Supplements pending MDUFA III Decision | 0 | 7 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | N/A | | | |

Table 3.2.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 20 | 7 | | | |
| Number with MDUFA decision | 19 | 0 | | | |
| Number of Not Approvable | 2 | 0 | | | |
| Rate of Not Approvable | 11% | N/A | | | |

Table 3.3.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 3.1.DMD DMD – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 90% within 90 FDA days | FY 2014 90% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|---|---|---|---|---|
| Supplements received | 13 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 13 | 1 | | | |
| MDUFA III Decisions within 90 FDA Days | 13 | 1 | | | |
| Supplements pending MDUFA III Decision | 0 | 0 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | 100% | | | |

Table 3.2.DMD DMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 13 | 1 | | | |
| Number with MDUFA decision | 13 | 1 | | | |
| Number of Not Approvable | 3 | 0 | | | |
| Rate of Not Approvable | 23% | 0% | | | |

Table 3.3.DMD DMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

There were no PMA 180 Day Supplements received by DRH between October 1, 2012 and December 31, 2013.

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2012 and December 31, 2013.

Section 5 PMA Annual Metrics and Goals

PMA Annual Metrics and Goals will be reported in the Annual Report.

Section 6 510(k) MDUFA III Performance

510(k) MDUFA III Performance – Center Level

Table 6.1 CDRH – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 2,965 | 885 | | | |
| Closed before RTA action | 12 | 3 | | | |
| Number Accepted | 1,197 | 314 | | | |
| RTA Review not done and > 15 days since Date Received | 41 | 7 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 158 | | | |
| Number Not Accepted | 1,715 | 403 | | | |
| Rate of submissions not accepted | 58% | 56% | | | |

* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2 CDRH – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 3,618 | 488 | | | |
| Deleted or withdrawn prior to SI | 11 | 0 | | | |
| SI within 60 FDA days | 3,294 | 192 | | | |
| SI over 60 FDA days | 209 | 0 | | | |
| SI pending within 60 FDA days | 98 | 293 | | | |
| SI pending over 60 FDA days | 2 | 3 | | | |
| 510(k)s NSE without SI | 4 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 94% | 98% | | | |

Table 6.3 CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 3,503 | 192 | | | |
| Average number of FDA days to Substantive Interaction | 47 | 38 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 30 | 26 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 47 | 29 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 56 | 44 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 59 | 54 | | | |
| Maximum FDA days to Substantive Interaction | 98 | 60 | | | |

Table 6.4 CDRH – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 3,746 | 505 | | | |
| Non-MDUFA III Decisions | 269 | 2 | | | |
| MDUFA III Decisions (SE/NSE) | 2,587 | 78 | | | |
| MDUFA III Decisions within 90 FDA Days | 2,556 | 78 | | | |
| 510(k)s pending MDUFA III Decision | 890 | 425 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 10 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 98% | 100% | | | |

Table 6.5 CDRH – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.64 | 1.08 | | | |
| Number with MDUFA decision | 2,587 | 78 | | | |
| Average FDA days to MDUFA III decision | 66 | 31 | | | |
| 20th Percentile FDA days to MDUFA III decision | 38 | 24 | | | |
| 40th Percentile FDA days to MDUFA III decision | 62 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 84 | 29 | | | |
| 80th Percentile FDA days to MDUFA III decision | 88 | 36 | | | |
| Maximum FDA days to MDUFA III decision | 200 | 60 | | | |
| Average Industry days to MDUFA III decision | 37 | 1 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 27 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 66 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 339 | 13 | | | |
| Average Total days to MDUFA III decision | 103 | 32 | | | |
| 20th Percentile Total days to MDUFA III decision | 42 | 24 | | | |
| 40th Percentile Total days to MDUFA III decision | 80 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 106 | 29 | | | |
| 80th Percentile Total days to MDUFA III decision | 147 | 37 | | | |
| Maximum Total days to MDUFA III decision | 429 | 71 | | | |

Table 6.6 CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 3,746 | 505 | | | |
| Number with MDUFA decision | 2,587 | 78 | | | |
| Number of SE decisions | 2,509 | 78 | | | |
| Number of NSE decisions | 78 | 0 | | | |
| Number of Withdrawals | 128 | 0 | | | |
| Number deleted | 122 | 0 | | | |
| Rate of SE decisions | 97% | 100% | | | |
| Rate of NSE decisions | 3% | 0% | | | |
| Rate of Withdrawals | 3% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7 CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 31 | 0 | | | |
| Mean FDA days for submissions that missed goal | 108 | | | | |
| Mean Industry days for submissions that missed goal | 98 | | | | |

510(k) MDUFA III Performance – Office Level

Table 6.1.ODE ODE – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 2,388 | 693 | | | |
| Closed before RTA action | 10 | 3 | | | |
| Number Accepted | 821 | 209 | | | |
| RTA Review not done and > 15 days since Date Received | 23 | 6 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 132 | | | |
| Number Not Accepted | 1,534 | 343 | | | |
| Rate of submissions not accepted | 65% | 61% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.ODE for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.ODE ODE – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 60 FDA days | FY 2014 75% SI within 60 FDA Days | FY 2015 85% SI within 60 FDA Days | FY 2016 95% SI within 60 FDA Days | FY 2017 95% SI within 60 FDA Days |
|---|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| Eligible for SI | 2,869 | 366 | | | |
| Deleted or withdrawn prior to SI | 10 | 0 | | | |
| SI within 60 FDA days | 2,596 | 138 | | | |
| SI over 60 FDA days | 166 | 0 | | | |
| SI pending within 60 FDA days | 91 | 226 | | | |
| SI pending over 60 FDA days | 2 | 2 | | | |
| 510(k)s NSE without SI | 4 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 94% | 99% | | | |

Table 6.3.ODE ODE – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2,762 | 138 | | | |
| Average number of FDA days to Substantive Interaction | 48 | 38 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 30 | 26 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 49 | 29 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 56 | 45 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 59 | 55 | | | |
| Maximum FDA days to Substantive Interaction | 98 | 60 | | | |

Table 6.4.ODE ODE – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 2,943 | 374 | | | |
| Non-MDUFA III Decisions | 226 | 2 | | | |
| MDUFA III Decisions (SE/NSE) | 1,985 | 54 | | | |
| MDUFA III Decisions within 90 FDA Days | 1,959 | 54 | | | |
| 510(k)s pending MDUFA III Decision | 732 | 318 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 10 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 98% | 100% | | | |

Table 6.5.ODE ODE – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.67 | 1.07 | | | |
| Number with MDUFA decision | 1,985 | 54 | | | |
| Average FDA days to MDUFA III decision | 68 | 30 | | | |
| 20th Percentile FDA days to MDUFA III decision | 44 | 24 | | | |
| 40th Percentile FDA days to MDUFA III decision | 67 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 85 | 29 | | | |
| 80th Percentile FDA days to MDUFA III decision | 89 | 35 | | | |
| Maximum FDA days to MDUFA III decision | 200 | 60 | | | |
| Average Industry days to MDUFA III decision | 37 | 1 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 6 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 29 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 66 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 321 | 13 | | | |
| Average Total days to MDUFA III decision | 105 | 31 | | | |
| 20th Percentile Total days to MDUFA III decision | 49 | 24 | | | |
| 40th Percentile Total days to MDUFA III decision | 85 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 110 | 29 | | | |
| 80th Percentile Total days to MDUFA III decision | 149 | 36 | | | |
| Maximum Total days to MDUFA III decision | 419 | 71 | | | |

Table 6.6.ODE ODE – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 2,943 | 374 | | | |
| Number with MDUFA decision | 1,985 | 54 | | | |
| Number of SE decisions | 1,920 | 54 | | | |
| Number of NSE decisions | 65 | 0 | | | |
| Number of Withdrawals | 108 | 0 | | | |
| Number deleted | 101 | 0 | | | |
| Rate of SE decisions | 97% | 100% | | | |
| Rate of NSE decisions | 3% | 0% | | | |
| Rate of Withdrawals | 4% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7.ODE ODE – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 26 | 0 | | | |
| Mean FDA days for submissions that missed goal | 108 | | | | |
| Mean Industry days for submissions that missed goal | 98 | | | | |

Table 6.1.OIR OIR – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 577 | 192 | | | |
| Closed before RTA action | 2 | 0 | | | |
| Number Accepted | 376 | 105 | | | |
| RTA Review not done and > 15 days since Date Received | 18 | 1 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 26 | | | |
| Number Not Accepted | 181 | 60 | | | |
| Rate of submissions not accepted | 31% | 36% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.OIR for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.OIR OIR – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 65% SI within 60 FDA days | FY 2014 75% SI within 60 FDA Days | FY 2015 85% SI within 60 FDA Days | FY 2016 95% SI within 60 FDA Days | FY 2017 95% SI within 60 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 749 | 122 | | | |
| Deleted or withdrawn prior to SI | 1 | 0 | | | |
| SI within 60 FDA days | 698 | 54 | | | |
| SI over 60 FDA days | 43 | 0 | | | |
| SI pending within 60 FDA days | 7 | 67 | | | |
| SI pending over 60 FDA days | 0 | 1 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 94% | 98% | | | |

Table 6.3.OIR OIR – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 741 | 54 | | | |
| Average number of FDA days to Substantive Interaction | 45 | 38 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 29 | 26 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 42 | 29 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 51 | 43 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 58 | 53 | | | |
| Maximum FDA days to Substantive Interaction | 91 | 60 | | | |

Table 6.4.OIR OIR – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 803 | 131 | | | |
| Non-MDUFA III Decisions | 43 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 602 | 24 | | | |
| MDUFA III Decisions within 90 FDA Days | 597 | 24 | | | |
| 510(k)s pending MDUFA III Decision | 158 | 107 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 6.5.OIR OIR – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.53 | 1.08 | | | |
| Number with MDUFA decision | 602 | 24 | | | |
| Average FDA days to MDUFA III decision | 60 | 31 | | | |
| 20th Percentile FDA days to MDUFA III decision | 30 | 26 | | | |
| 40th Percentile FDA days to MDUFA III decision | 51 | 28 | | | |
| 60th Percentile FDA days to MDUFA III decision | 76 | 30 | | | |
| 80th Percentile FDA days to MDUFA III decision | 86 | 35 | | | |
| Maximum FDA days to MDUFA III decision | 121 | 49 | | | |
| Average Industry days to MDUFA III decision | 35 | 1 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 18 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 64 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 339 | 13 | | | |
| Average Total days to MDUFA III decision | 95 | 32 | | | |
| 20th Percentile Total days to MDUFA III decision | 31 | 26 | | | |
| 40th Percentile Total days to MDUFA III decision | 63 | 28 | | | |
| 60th Percentile Total days to MDUFA III decision | 89 | 31 | | | |
| 80th Percentile Total days to MDUFA III decision | 139 | 39 | | | |
| Maximum Total days to MDUFA III decision | 429 | 49 | | | |

Table 6.6.OIR OIR – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 803 | 131 | | | |
| Number with MDUFA decision | 602 | 24 | | | |
| Number of SE decisions | 589 | 24 | | | |
| Number of NSE decisions | 13 | 0 | | | |
| Number of Withdrawals | 20 | 0 | | | |
| Number deleted | 21 | 0 | | | |
| Rate of SE decisions | 98% | 100% | | | |
| Rate of NSE decisions | 2% | 0% | | | |
| Rate of Withdrawals | 2% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7.OIR OIR – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 5 | 0 | | | |
| Mean FDA days for submissions that missed goal | 104 | | | | |
| Mean Industry days for submissions that missed goal | 99 | | | | |

510(k) MDUFA III Performance – Division Level

Table 6.1.DAGRID DAGRID – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 636 | 153 | | | |
| Closed before RTA action | 6 | 1 | | | |
| Number Accepted | 189 | 31 | | | |
| RTA Review not done and > 15 days since Date Received | 5 | 2 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 24 | | | |
| Number Not Accepted | 436 | 95 | | | |
| Rate of submissions not accepted | 69% | 74% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DAGRID for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DAGRID DAGRID – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 739 | 68 | | | |
| Deleted or withdrawn prior to SI | 0 | 0 | | | |
| SI within 60 FDA days | 681 | 13 | | | |
| SI over 60 FDA days | 25 | 0 | | | |
| SI pending within 60 FDA days | 31 | 55 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 2 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 96% | 100% | | | |

Table 6.3.DAGRID DAGRID – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 706 | 13 | | | |
| Average number of FDA days to Substantive Interaction | 50 | 38 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 41 | 25 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 54 | 28 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 58 | 44 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 60 | 56 | | | |
| Maximum FDA days to Substantive Interaction | 90 | 60 | | | |

Table 6.4.DAGRID DAGRID – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 754 | 70 | | | |
| Non-MDUFA III Decisions | 75 | 1 | | | |
| MDUFA III Decisions (SE/NSE) | 438 | 6 | | | |
| MDUFA III Decisions within 90 FDA Days | 431 | 6 | | | |
| 510(k)s pending MDUFA III Decision | 241 | 63 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 4 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 98% | 100% | | | |

Table 6.5.DAGRID DAGRID – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.70 | 1.17 | | | |
| Number with MDUFA decision | 438 | 6 | | | |
| Average FDA days to MDUFA III decision | 73 | 25 | | | |
| 20th Percentile FDA days to MDUFA III decision | 56 | 23 | | | |
| 40th Percentile FDA days to MDUFA III decision | 80 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 87 | 27 | | | |
| 80th Percentile FDA days to MDUFA III decision | 89 | 28 | | | |
| Maximum FDA days to MDUFA III decision | 150 | 28 | | | |
| Average Industry days to MDUFA III decision | 40 | 2 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 10 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 30 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 70 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 263 | 10 | | | |
| Average Total days to MDUFA III decision | 113 | 26 | | | |
| 20th Percentile Total days to MDUFA III decision | 65 | 23 | | | |
| 40th Percentile Total days to MDUFA III decision | 89 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 114 | 28 | | | |
| 80th Percentile Total days to MDUFA III decision | 151 | 28 | | | |
| Maximum Total days to MDUFA III decision | 352 | 37 | | | |

Table 6.6.DAGRID DAGRID – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 754 | 70 | | | |
| Number with MDUFA decision | 438 | 6 | | | |
| Number of SE decisions | 423 | 6 | | | |
| Number of NSE decisions | 15 | 0 | | | |
| Number of Withdrawals | 29 | 0 | | | |
| Number deleted | 42 | 0 | | | |
| Rate of SE decisions | 97% | 100% | | | |
| Rate of NSE decisions | 3% | 0% | | | |
| Rate of Withdrawals | 4% | 0% | | | |
| Rate of Deleted | 6% | 0% | | | |

Table 6.7.DAGRID DAGRID – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 7 | 0 | | | |
| Mean FDA days for submissions that missed goal | 105 | | | | |
| Mean Industry days for submissions that missed goal | 105 | | | | |

Table 6.1.DCD DCD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 336 | 105 | | | |
| Closed before RTA action | 1 | 0 | | | |
| Number Accepted | 151 | 30 | | | |
| RTA Review not done and > 15 days since Date Received | 9 | 0 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 29 | | | |
| Number Not Accepted | 175 | 46 | | | |
| Rate of submissions not accepted | 52% | 61% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DCD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DCD DCD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 424 | 56 | | | |
| Deleted or withdrawn prior to SI | 1 | 0 | | | |
| SI within 60 FDA days | 375 | 27 | | | |
| SI over 60 FDA days | 38 | 0 | | | |
| SI pending within 60 FDA days | 10 | 29 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 91% | 100% | | | |

Table 6.3.DCD DCD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 413 | 27 | | | |
| Average number of FDA days to Substantive Interaction | 45 | 32 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 29 | 25 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 42 | 29 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 50 | 30 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 58 | 48 | | | |
| Maximum FDA days to Substantive Interaction | 98 | 56 | | | |

Table 6.4.DCD DCD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 448 | 59 | | | |
| Non-MDUFA III Decisions | 10 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 360 | 16 | | | |
| MDUFA III Decisions within 90 FDA Days | 352 | 16 | | | |
| 510(k)s pending MDUFA III Decision | 78 | 43 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 3 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 97% | 100% | | | |

Table 6.5.DCD DCD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.64 | 1.06 | | | |
| Number with MDUFA decision | 360 | 16 | | | |
| Average FDA days to MDUFA III decision | 63 | 32 | | | |
| 20th Percentile FDA days to MDUFA III decision | 30 | 24 | | | |
| 40th Percentile FDA days to MDUFA III decision | 54 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 82 | 29 | | | |
| 80th Percentile FDA days to MDUFA III decision | 89 | 30 | | | |
| Maximum FDA days to MDUFA III decision | 200 | 60 | | | |
| Average Industry days to MDUFA III decision | 32 | 1 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 28 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 56 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 321 | 11 | | | |
| Average Total days to MDUFA III decision | 95 | 32 | | | |
| 20th Percentile Total days to MDUFA III decision | 30 | 24 | | | |
| 40th Percentile Total days to MDUFA III decision | 69 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 104 | 29 | | | |
| 80th Percentile Total days to MDUFA III decision | 139 | 30 | | | |
| Maximum Total days to MDUFA III decision | 419 | 71 | | | |

Table 6.6.DCD DCD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 448 | 59 | | | |
| Number with MDUFA decision | 360 | 16 | | | |
| Number of SE decisions | 352 | 16 | | | |
| Number of NSE decisions | 8 | 0 | | | |
| Number of Withdrawals | 4 | 0 | | | |
| Number deleted | 6 | 0 | | | |
| Rate of SE decisions | 98% | 100% | | | |
| Rate of NSE decisions | 2% | 0% | | | |
| Rate of Withdrawals | 1% | 0% | | | |
| Rate of Deleted | 1% | 0% | | | |

Table 6.7.DCD DCD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 8 | 0 | | | |
| Mean FDA days for submissions that missed goal | 117 | | | | |
| Mean Industry days for submissions that missed goal | 77 | | | | |

Table 6.1.DNPMD DNPMD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 189 | 55 | | | |
| Closed before RTA action | 0 | 1 | | | |
| Number Accepted | 39 | 16 | | | |
| RTA Review not done and > 15 days since Date Received | 1 | 1 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 14 | | | |
| Number Not Accepted | 149 | 23 | | | |
| Rate of submissions not accepted | 79% | 58% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DNPMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DNPMD DNPMD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 216 | 22 | | | |
| Deleted or withdrawn prior to SI | 2 | 0 | | | |
| SI within 60 FDA days | 174 | 7 | | | |
| SI over 60 FDA days | 22 | 0 | | | |
| SI pending within 60 FDA days | 16 | 15 | | | |
| SI pending over 60 FDA days | 2 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 88% | 100% | | | |

Table 6.3.DNPMD DNPMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 196 | 7 | | | |
| Average number of FDA days to Substantive Interaction | 51 | 54 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 42 | 55 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 52 | 57 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 58 | 59 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 60 | 60 | | | |
| Maximum FDA days to Substantive Interaction | 80 | 60 | | | |

Table 6.4.DNPMD DNPMD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 222 | 22 | | | |
| Non-MDUFA III Decisions | 19 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 127 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 125 | 0 | | | |
| 510(k)s pending MDUFA III Decision | 76 | 22 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 98% | n/a | | | |

Table 6.5.DNPMD DNPMD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.83 | 0.00 | | | |
| Number with MDUFA decision | 127 | 0 | | | |
| Average FDA days to MDUFA III decision | 81 | | | | |
| 20th Percentile FDA days to MDUFA III decision | 70 | | | | |
| 40th Percentile FDA days to MDUFA III decision | 88 | | | | |
| 60th Percentile FDA days to MDUFA III decision | 89 | | | | |
| 80th Percentile FDA days to MDUFA III decision | 90 | | | | |
| Maximum FDA days to MDUFA III decision | 148 | | | | |
| Average Industry days to MDUFA III decision | 53 | | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40th Percentile Industry days to MDUFA III decision | 22 | | | | |
| 60th Percentile Industry days to MDUFA III decision | 52 | | | | |
| 80th Percentile Industry days to MDUFA III decision | 93 | | | | |
| Maximum Industry days to MDUFA III decision | 180 | | | | |
| Average Total days to MDUFA III decision | 134 | | | | |
| 20th Percentile Total days to MDUFA III decision | 88 | | | | |
| 40th Percentile Total days to MDUFA III decision | 108 | | | | |
| 60th Percentile Total days to MDUFA III decision | 133 | | | | |
| 80th Percentile Total days to MDUFA III decision | 182 | | | | |
| Maximum Total days to MDUFA III decision | 270 | | | | |

Table 6.6.DNPMD DNPMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 222 | 22 | | | |
| Number with MDUFA decision | 127 | 0 | | | |
| Number of SE decisions | 120 | 0 | | | |
| Number of NSE decisions | 7 | 0 | | | |
| Number of Withdrawals | 9 | 0 | | | |
| Number deleted | 5 | 0 | | | |
| Rate of SE decisions | 94% | n/a | | | |
| Rate of NSE decisions | 6% | n/a | | | |
| Rate of Withdrawals | 4% | n/a | | | |
| Rate of Deleted | 2% | n/a | | | |

Table 6.7.DNPMD DNPMD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 2 | 0 | | | |
| Mean FDA days for submissions that missed goal | 120 | | | | |
| Mean Industry days for submissions that missed goal | 86 | | | | |

Table 6.1.DOD DOD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 523 | 163 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number Accepted | 181 | 55 | | | |
| RTA Review not done and > 15 days since Date Received | 0 | 2 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 21 | | | |
| Number Not Accepted | 342 | 85 | | | |
| Rate of submissions not accepted | 65% | 60% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DOD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DOD DOD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 647 | 103 | | | |
| Deleted or withdrawn prior to SI | 3 | 0 | | | |
| SI within 60 FDA days | 603 | 41 | | | |
| SI over 60 FDA days | 28 | 0 | | | |
| SI pending within 60 FDA days | 13 | 62 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 96% | 100% | | | |

Table 6.3.DOD DOD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 631 | 41 | | | |
| Average number of FDA days to Substantive Interaction | 48 | 36 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 30 | 26 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 48 | 29 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 56 | 36 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 59 | 52 | | | |
| Maximum FDA days to Substantive Interaction | 88 | 59 | | | |

Table 6.4.DOD DOD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 648 | 103 | | | |
| Non-MDUFA III Decisions | 42 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 492 | 15 | | | |
| MDUFA III Decisions within 90 FDA Days | 489 | 15 | | | |
| 510(k)s pending MDUFA III Decision | 114 | 88 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 6.5.DOD DOD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.55 | 1.00 | | | |
| Number with MDUFA decision | 492 | 15 | | | |
| Average FDA days to MDUFA III decision | 67 | 30 | | | |
| 20th Percentile FDA days to MDUFA III decision | 44 | 24 | | | |
| 40th Percentile FDA days to MDUFA III decision | 63 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 82 | 28 | | | |
| 80th Percentile FDA days to MDUFA III decision | 88 | 31 | | | |
| Maximum FDA days to MDUFA III decision | 100 | 56 | | | |
| Average Industry days to MDUFA III decision | 28 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 19 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 48 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 211 | 0 | | | |
| Average Total days to MDUFA III decision | 95 | 30 | | | |
| 20th Percentile Total days to MDUFA III decision | 44 | 24 | | | |
| 40th Percentile Total days to MDUFA III decision | 76 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 98 | 28 | | | |
| 80th Percentile Total days to MDUFA III decision | 130 | 31 | | | |
| Maximum Total days to MDUFA III decision | 293 | 56 | | | |

Table 6.6.DOD DOD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 648 | 103 | | | |
| Number with MDUFA decision | 492 | 15 | | | |
| Number of SE decisions | 480 | 15 | | | |
| Number of NSE decisions | 12 | 0 | | | |
| Number of Withdrawals | 23 | 0 | | | |
| Number deleted | 18 | 0 | | | |
| Rate of SE decisions | 98% | 100% | | | |
| Rate of NSE decisions | 2% | 0% | | | |
| Rate of Withdrawals | 4% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7.DOD DOD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 3 | 0 | | | |
| Mean FDA days for submissions that missed goal | 96 | | | | |
| Mean Industry days for submissions that missed goal | 103 | | | | |

Table 6.1.DOED DOED – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 118 | 34 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number Accepted | 59 | 17 | | | |
| RTA Review not done and > 15 days since Date Received | 5 | 0 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 5 | | | |
| Number Not Accepted | 54 | 12 | | | |
| Rate of submissions not accepted | 46% | 41% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DOED for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DOED DOED – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 135 | 21 | | | |
| Deleted or withdrawn prior to SI | 0 | 0 | | | |
| SI within 60 FDA days | 128 | 11 | | | |
| SI over 60 FDA days | 5 | 0 | | | |
| SI pending within 60 FDA days | 2 | 10 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 96% | 100% | | | |

Table 6.3.DOED DOED – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 133 | 11 | | | |
| Average number of FDA days to Substantive Interaction | 48 | 47 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 42 | 30 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 48 | 45 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 53 | 56 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 57 | 57 | | | |
| Maximum FDA days to Substantive Interaction | 88 | 60 | | | |

Table 6.4.DOED DOED – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 142 | 21 | | | |
| Non-MDUFA III Decisions | 14 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 94 | 3 | | | |
| MDUFA III Decisions within 90 FDA Days | 91 | 3 | | | |
| 510(k)s pending MDUFA III Decision | 34 | 18 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 97% | 100% | | | |

Table 6.5.DOE DOED – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.78 | 1.00 | | | |
| Number with MDUFA decision | 94 | 3 | | | |
| Average FDA days to MDUFA III decision | 72 | 38 | | | |
| 20th Percentile FDA days to MDUFA III decision | 53 | 28 | | | |
| 40th Percentile FDA days to MDUFA III decision | 73 | 29 | | | |
| 60th Percentile FDA days to MDUFA III decision | 87 | 35 | | | |
| 80th Percentile FDA days to MDUFA III decision | 89 | 46 | | | |
| Maximum FDA days to MDUFA III decision | 91 | 56 | | | |
| Average Industry days to MDUFA III decision | 43 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 10 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 34 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 72 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 182 | 0 | | | |
| Average Total days to MDUFA III decision | 115 | 38 | | | |
| 20th Percentile Total days to MDUFA III decision | 58 | 28 | | | |
| 40th Percentile Total days to MDUFA III decision | 90 | 29 | | | |
| 60th Percentile Total days to MDUFA III decision | 119 | 35 | | | |
| 80th Percentile Total days to MDUFA III decision | 152 | 46 | | | |
| Maximum Total days to MDUFA III decision | 272 | 56 | | | |

Table 6.6.DOED DOED – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 142 | 21 | | | |
| Number with MDUFA decision | 94 | 3 | | | |
| Number of SE decisions | 92 | 3 | | | |
| Number of NSE decisions | 2 | 0 | | | |
| Number of Withdrawals | 6 | 0 | | | |
| Number deleted | 7 | 0 | | | |
| Rate of SE decisions | 98% | 100% | | | |
| Rate of NSE decisions | 2% | 0% | | | |
| Rate of Withdrawals | 4% | 0% | | | |
| Rate of Deleted | 5% | 0% | | | |

Table 6.7.DOED DOED – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 3 | 0 | | | |
| Mean FDA days for submissions that missed goal | 91 | | | | |
| Mean Industry days for submissions that missed goal | 123 | | | | |

Table 6.1.DRGUD DRGUD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 211 | 75 | | | |
| Closed before RTA action | 0 | 1 | | | |
| Number Accepted | 66 | 28 | | | |
| RTA Review not done and > 15 days since Date Received | 0 | 1 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 17 | | | |
| Number Not Accepted | 145 | 28 | | | |
| Rate of submissions not accepted | 69% | 49% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DRGUD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DRGUD DRGUD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 251 | 40 | | | |
| Deleted or withdrawn prior to SI | 1 | 0 | | | |
| SI within 60 FDA days | 232 | 15 | | | |
| SI over 60 FDA days | 8 | 0 | | | |
| SI pending within 60 FDA days | 8 | 24 | | | |
| SI pending over 60 FDA days | 0 | 1 | | | |
| 510(k)s NSE without SI | 2 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 96% | 94% | | | |

Table 6.3.DRGUD DRGUD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 240 | 15 | | | |
| Average number of FDA days to Substantive Interaction | 47 | 39 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 33 | 24 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 49 | 30 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 55 | 53 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 58 | 57 | | | |
| Maximum FDA days to Substantive Interaction | 73 | 60 | | | |

Table 6.4.DRGUD DRGUD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 264 | 42 | | | |
| Non-MDUFA III Decisions | 20 | 1 | | | |
| MDUFA III Decisions (SE/NSE) | 170 | 3 | | | |
| MDUFA III Decisions within 90 FDA Days | 170 | 3 | | | |
| 510(k)s pending MDUFA III Decision | 74 | 38 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 1 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 6.5.DRGUD DRGUD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.79 | 1.33 | | | |
| Number with MDUFA decision | 170 | 3 | | | |
| Average FDA days to MDUFA III decision | 66 | 25 | | | |
| 20th Percentile FDA days to MDUFA III decision | 39 | 15 | | | |
| 40th Percentile FDA days to MDUFA III decision | 64 | 21 | | | |
| 60th Percentile FDA days to MDUFA III decision | 83 | 28 | | | |
| 80th Percentile FDA days to MDUFA III decision | 87 | 35 | | | |
| Maximum FDA days to MDUFA III decision | 90 | 43 | | | |
| Average Industry days to MDUFA III decision | 48 | 4 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 15 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 38 | 3 | | | |
| 80th Percentile Industry days to MDUFA III decision | 92 | 8 | | | |
| Maximum Industry days to MDUFA III decision | 274 | 13 | | | |
| Average Total days to MDUFA III decision | 114 | 30 | | | |
| 20th Percentile Total days to MDUFA III decision | 55 | 15 | | | |
| 40th Percentile Total days to MDUFA III decision | 87 | 21 | | | |
| 60th Percentile Total days to MDUFA III decision | 119 | 30 | | | |
| 80th Percentile Total days to MDUFA III decision | 170 | 43 | | | |
| Maximum Total days to MDUFA III decision | 362 | 56 | | | |

Table 6.6.DRGUD DRGUD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 264 | 42 | | | |
| Number with MDUFA decision | 170 | 3 | | | |
| Number of SE decisions | 159 | 3 | | | |
| Number of NSE decisions | 11 | 0 | | | |
| Number of Withdrawals | 11 | 0 | | | |
| Number deleted | 8 | 0 | | | |
| Rate of SE decisions | 94% | 100% | | | |
| Rate of NSE decisions | 6% | 0% | | | |
| Rate of Withdrawals | 4% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7.DRGUD DRGUD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 6.1.DSD DSD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 375 | 108 | | | |
| Closed before RTA action | 3 | 0 | | | |
| Number Accepted | 136 | 32 | | | |
| RTA Review not done and > 15 days since Date Received | 3 | 0 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 22 | | | |
| Number Not Accepted | 233 | 54 | | | |
| Rate of submissions not accepted | 63% | 63% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DSD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DSD DSD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 457 | 56 | | | |
| Deleted or withdrawn prior to SI | 3 | 0 | | | |
| SI within 60 FDA days | 403 | 24 | | | |
| SI over 60 FDA days | 40 | 0 | | | |
| SI pending within 60 FDA days | 11 | 31 | | | |
| SI pending over 60 FDA days | 0 | 1 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 91% | 96% | | | |

Table 6.3.DSD DSD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 443 | 24 | | | |
| Average number of FDA days to Substantive Interaction | 45 | 38 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 27 | 27 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 43 | 30 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 55 | 46 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 59 | 50 | | | |
| Maximum FDA days to Substantive Interaction | 90 | 57 | | | |

Table 6.4.DSD DSD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 465 | 57 | | | |
| Non-MDUFA III Decisions | 46 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 304 | 11 | | | |
| MDUFA III Decisions within 90 FDA Days | 301 | 11 | | | |
| 510(k)s pending MDUFA III Decision | 115 | 46 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 2 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 98% | 100% | | | |

Table 6.5.DSD DSD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.68 | 1.09 | | | |
| Number with MDUFA decision | 304 | 11 | | | |
| Average FDA days to MDUFA III decision | 62 | 32 | | | |
| 20th Percentile FDA days to MDUFA III decision | 30 | 21 | | | |
| 40th Percentile FDA days to MDUFA III decision | 58 | 26 | | | |
| 60th Percentile FDA days to MDUFA III decision | 79 | 29 | | | |
| 80th Percentile FDA days to MDUFA III decision | 87 | 45 | | | |
| Maximum FDA days to MDUFA III decision | 150 | 51 | | | |
| Average Industry days to MDUFA III decision | 40 | 1 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 8 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 28 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 74 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 298 | 13 | | | |
| Average Total days to MDUFA III decision | 102 | 33 | | | |
| 20th Percentile Total days to MDUFA III decision | 37 | 21 | | | |
| 40th Percentile Total days to MDUFA III decision | 74 | 26 | | | |
| 60th Percentile Total days to MDUFA III decision | 109 | 29 | | | |
| 80th Percentile Total days to MDUFA III decision | 150 | 50 | | | |
| Maximum Total days to MDUFA III decision | 396 | 58 | | | |

Table 6.6.DSD DSD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 465 | 57 | | | |
| Number with MDUFA decision | 304 | 11 | | | |
| Number of SE decisions | 294 | 11 | | | |
| Number of NSE decisions | 10 | 0 | | | |
| Number of Withdrawals | 26 | 0 | | | |
| Number deleted | 15 | 0 | | | |
| Rate of SE decisions | 97% | 100% | | | |
| Rate of NSE decisions | 3% | 0% | | | |
| Rate of Withdrawals | 6% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7.DSD DSD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 3 | 0 | | | |
| Mean FDA days for submissions that missed goal | 114 | | | | |
| Mean Industry days for submissions that missed goal | 112 | | | | |

Table 6.1.DCTD DCTD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 188 | 51 | | | |
| Closed before RTA action | 1 | 0 | | | |
| Number Accepted | 118 | 30 | | | |
| RTA Review not done and > 15 days since Date Received | 0 | 1 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 6 | | | |
| Number Not Accepted | 69 | 14 | | | |
| Rate of submissions not accepted | 37% | 31% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DCTD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DCTD DCTD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 243 | 35 | | | |
| Deleted or withdrawn prior to SI | 0 | 0 | | | |
| SI within 60 FDA days | 242 | 16 | | | |
| SI over 60 FDA days | 0 | 0 | | | |
| SI pending within 60 FDA days | 1 | 19 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 100% | 100% | | | |

Table 6.3.DCTD DCTD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 242 | 16 | | | |
| Average number of FDA days to Substantive Interaction | 41 | 35 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 28 | 25 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 38 | 28 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 45 | 39 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 52 | 50 | | | |
| Maximum FDA days to Substantive Interaction | 60 | 54 | | | |

Table 6.4.DCTD DCTD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 243 | 35 | | | |
| Non-MDUFA III Decisions | 13 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 165 | 3 | | | |
| MDUFA III Decisions within 90 FDA Days | 164 | 3 | | | |
| 510(k)s pending MDUFA III Decision | 65 | 32 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 6.5.DCTD DCTD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.63 | 1.00 | | | |
| Number with MDUFA decision | 165 | 3 | | | |
| Average FDA days to MDUFA III decision | 59 | 27 | | | |
| 20th Percentile FDA days to MDUFA III decision | 30 | 26 | | | |
| 40th Percentile FDA days to MDUFA III decision | 49 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 77 | 28 | | | |
| 80th Percentile FDA days to MDUFA III decision | 86 | 28 | | | |
| Maximum FDA days to MDUFA III decision | 99 | 28 | | | |
| Average Industry days to MDUFA III decision | 46 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 32 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 87 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 307 | 0 | | | |
| Average Total days to MDUFA III decision | 105 | 27 | | | |
| 20th Percentile Total days to MDUFA III decision | 30 | 26 | | | |
| 40th Percentile Total days to MDUFA III decision | 54 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 105 | 28 | | | |
| 80th Percentile Total days to MDUFA III decision | 168 | 28 | | | |
| Maximum Total days to MDUFA III decision | 395 | 28 | | | |

Table 6.6.DCTD DCTD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 243 | 35 | | | |
| Number with MDUFA decision | 165 | 3 | | | |
| Number of SE decisions | 162 | 3 | | | |
| Number of NSE decisions | 3 | 0 | | | |
| Number of Withdrawals | 9 | 0 | | | |
| Number deleted | 4 | 0 | | | |
| Rate of SE decisions | 98% | 100% | | | |
| Rate of NSE decisions | 2% | 0% | | | |
| Rate of Withdrawals | 4% | 0% | | | |
| Rate of Deleted | 2% | 0% | | | |

Table 6.7.DCTD DCTD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 1 | 0 | | | |
| Mean FDA days for submissions that missed goal | 99 | | | | |
| Mean Industry days for submissions that missed goal | 193 | | | | |

Table 6.1.DIHD DIHD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 73 | 18 | | | |
| Closed before RTA action | 1 | 0 | | | |
| Number Accepted | 52 | 8 | | | |
| RTA Review not done and > 15 days since Date Received | 3 | 0 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 3 | | | |
| Number Not Accepted | 17 | 7 | | | |
| Rate of submissions not accepted | 24% | 47% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DIHD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DIHD DIHD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 86 | 8 | | | |
| Deleted or withdrawn prior to SI | 0 | 0 | | | |
| SI within 60 FDA days | 83 | 3 | | | |
| SI over 60 FDA days | 1 | 0 | | | |
| SI pending within 60 FDA days | 2 | 5 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 99% | 100% | | | |

Table 6.3.DIHD DIHD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 84 | 3 | | | |
| Average number of FDA days to Substantive Interaction | 48 | 42 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 41 | 31 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 50 | 41 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 55 | 48 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 58 | 53 | | | |
| Maximum FDA days to Substantive Interaction | 63 | 58 | | | |

Table 6.4.DIHD DIHD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 86 | 8 | | | |
| Non-MDUFA III Decisions | 17 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 40 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 40 | 0 | | | |
| 510(k)s pending MDUFA III Decision | 29 | 8 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | n/a | | | |

Table 6.5.DIHD DIHD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.88 | 0.00 | | | |
| Number with MDUFA decision | 40 | 0 | | | |
| Average FDA days to MDUFA III decision | 69 | | | | |
| 20th Percentile FDA days to MDUFA III decision | 49 | | | | |
| 40th Percentile FDA days to MDUFA III decision | 74 | | | | |
| 60th Percentile FDA days to MDUFA III decision | 83 | | | | |
| 80th Percentile FDA days to MDUFA III decision | 88 | | | | |
| Maximum FDA days to MDUFA III decision | 90 | | | | |
| Average Industry days to MDUFA III decision | 94 | | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | | | | |
| 40th Percentile Industry days to MDUFA III decision | 55 | | | | |
| 60th Percentile Industry days to MDUFA III decision | 129 | | | | |
| 80th Percentile Industry days to MDUFA III decision | 169 | | | | |
| Maximum Industry days to MDUFA III decision | 253 | | | | |
| Average Total days to MDUFA III decision | 164 | | | | |
| 20th Percentile Total days to MDUFA III decision | 77 | | | | |
| 40th Percentile Total days to MDUFA III decision | 118 | | | | |
| 60th Percentile Total days to MDUFA III decision | 215 | | | | |
| 80th Percentile Total days to MDUFA III decision | 255 | | | | |
| Maximum Total days to MDUFA III decision | 328 | | | | |

Table 6.6.DIHD DIHD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 86 | 8 | | | |
| Number with MDUFA decision | 40 | 0 | | | |
| Number of SE decisions | 36 | 0 | | | |
| Number of NSE decisions | 4 | 0 | | | |
| Number of Withdrawals | 2 | 0 | | | |
| Number deleted | 13 | 0 | | | |
| Rate of SE decisions | 90% | n/a | | | |
| Rate of NSE decisions | 10% | n/a | | | |
| Rate of Withdrawals | 2% | n/a | | | |
| Rate of Deleted | 15% | n/a | | | |

Table 6.7.DIHD DIHD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 6.1.DMD DMD – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-----------------|----------------|----------------|----------------|----------------|
| Number Received | 59 | 21 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number Accepted | 55 | 17 | | | |
| RTA Review not done and > 15 days since Date Received | 0 | 0 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 4 | | | |
| Number Not Accepted | 4 | 0 | | | |
| Rate of submissions not accepted | 7% | 0% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DMD DMD – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 80 | 17 | | | |
| Deleted or withdrawn prior to SI | 0 | 0 | | | |
| SI within 60 FDA days | 79 | 10 | | | |
| SI over 60 FDA days | 1 | 0 | | | |
| SI pending within 60 FDA days | 0 | 7 | | | |
| SI pending over 60 FDA days | 0 | 0 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 99% | 100% | | | |

Table 6.3.DMD DMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 80 | 10 | | | |
| Average number of FDA days to Substantive Interaction | 43 | 31 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 28 | 25 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 39 | 28 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 53 | 28 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 57 | 31 | | | |
| Maximum FDA days to Substantive Interaction | 61 | 59 | | | |

Table 6.4.DMD DMD – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 91% within 90 FDA days | FY 2014 93% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|--|--|--|--|--|
| 510(k)s accepted | 80 | 17 | | | |
| Non-MDUFA III Decisions | 4 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 66 | 7 | | | |
| MDUFA III Decisions within 90 FDA Days | 66 | 7 | | | |
| 510(k)s pending MDUFA III Decision | 10 | 10 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100% | 100% | | | |

Table 6.5.DMD DMD – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.26 | 1.00 | | | |
| Number with MDUFA decision | 66 | 7 | | | |
| Average FDA days to MDUFA III decision | 57 | 28 | | | |
| 20th Percentile FDA days to MDUFA III decision | 29 | 25 | | | |
| 40th Percentile FDA days to MDUFA III decision | 42 | 27 | | | |
| 60th Percentile FDA days to MDUFA III decision | 76 | 29 | | | |
| 80th Percentile FDA days to MDUFA III decision | 81 | 29 | | | |
| Maximum FDA days to MDUFA III decision | 89 | 36 | | | |
| Average Industry days to MDUFA III decision | 26 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 48 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 175 | 0 | | | |
| Average Total days to MDUFA III decision | 83 | 28 | | | |
| 20th Percentile Total days to MDUFA III decision | 29 | 25 | | | |
| 40th Percentile Total days to MDUFA III decision | 47 | 27 | | | |
| 60th Percentile Total days to MDUFA III decision | 80 | 28 | | | |
| 80th Percentile Total days to MDUFA III decision | 122 | 29 | | | |
| Maximum Total days to MDUFA III decision | 256 | 36 | | | |

Table 6.6.DMD DMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 80 | 17 | | | |
| Number with MDUFA decision | 66 | 7 | | | |
| Number of SE decisions | 66 | 7 | | | |
| Number of NSE decisions | 0 | 0 | | | |
| Number of Withdrawals | 2 | 0 | | | |
| Number deleted | 2 | 0 | | | |
| Rate of SE decisions | 100% | 100% | | | |
| Rate of NSE decisions | 0% | 0% | | | |
| Rate of Withdrawals | 3% | 0% | | | |
| Rate of Deleted | 3% | 0% | | | |

Table 6.7.DMD DMD – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | | | | | |
| Mean Industry days for submissions that missed goal | | | | | |

Table 6.1.DRH DRH – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013* | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------|---------|---------|---------|---------|
| Number Received | 257 | 102 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number Accepted | 151 | 50 | | | |
| RTA Review not done and > 15 days since Date Received | 15 | 0 | | | |
| RTA Review not done and <= 15 days since Date Received | 0 | 13 | | | |
| Number Not Accepted | 91 | 39 | | | |
| Rate of submissions not accepted | 35% | 44% | | | |

* RTA was not in place 1st quarter, thus Table 6.1.DRH for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

Table 6.2.DRH DRH – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA Days | 85% SI within 60 FDA Days | 95% SI within 60 FDA Days | 95% SI within 60 FDA Days |
| Eligible for SI | 340 | 62 | | | |
| Deleted or withdrawn prior to SI | 1 | 0 | | | |
| SI within 60 FDA days | 294 | 25 | | | |
| SI over 60 FDA days | 41 | 0 | | | |
| SI pending within 60 FDA days | 4 | 36 | | | |
| SI pending over 60 FDA days | 0 | 1 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 88% | 96% | | | |

Table 6.3.DRH DRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 335 | 25 | | | |
| Average number of FDA days to Substantive Interaction | 47 | 42 | | | |
| 20 th Percentile FDA days to Substantive Interaction | 31 | 29 | | | |
| 40 th Percentile FDA days to Substantive Interaction | 44 | 38 | | | |
| 60 th Percentile FDA days to Substantive Interaction | 56 | 46 | | | |
| 80 th Percentile FDA days to Substantive Interaction | 59 | 56 | | | |
| Maximum FDA days to Substantive Interaction | 91 | 60 | | | |

Table 6.4.DRH DRH – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 91% within 90 FDA days | FY 2014 93% within 90 FDA days | FY 2015 95% within 90 FDA days | FY 2016 95% within 90 FDA days | FY 2017 95% within 90 FDA days |
|--|--|--|--|--|--|
| 510(k)s accepted | 394 | 71 | | | |
| Non-MDUFA III Decisions | 9 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 331 | 14 | | | |
| MDUFA III Decisions within 90 FDA Days | 327 | 14 | | | |
| 510(k)s pending MDUFA III Decision | 54 | 57 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 99% | 100% | | | |

Table 6.5.DRH DRH – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average review cycles | 1.50 | 1.14 | | | |
| Number with MDUFA decision | 331 | 14 | | | |
| Average FDA days to MDUFA III decision | 59 | 34 | | | |
| 20th Percentile FDA days to MDUFA III decision | 31 | 29 | | | |
| 40th Percentile FDA days to MDUFA III decision | 52 | 30 | | | |
| 60th Percentile FDA days to MDUFA III decision | 73 | 33 | | | |
| 80th Percentile FDA days to MDUFA III decision | 87 | 45 | | | |
| Maximum FDA days to MDUFA III decision | 121 | 49 | | | |
| Average Industry days to MDUFA III decision | 24 | 1 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 12 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 40 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 339 | 13 | | | |
| Average Total days to MDUFA III decision | 84 | 35 | | | |
| 20th Percentile Total days to MDUFA III decision | 34 | 29 | | | |
| 40th Percentile Total days to MDUFA III decision | 63 | 31 | | | |
| 60th Percentile Total days to MDUFA III decision | 85 | 34 | | | |
| 80th Percentile Total days to MDUFA III decision | 114 | 45 | | | |
| Maximum Total days to MDUFA III decision | 429 | 49 | | | |

Table 6.6.DRH DRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 394 | 71 | | | |
| Number with MDUFA decision | 331 | 14 | | | |
| Number of SE decisions | 325 | 14 | | | |
| Number of NSE decisions | 6 | 0 | | | |
| Number of Withdrawals | 7 | 0 | | | |
| Number deleted | 2 | 0 | | | |
| Rate of SE decisions | 98% | 100% | | | |
| Rate of NSE decisions | 2% | 0% | | | |
| Rate of Withdrawals | 2% | 0% | | | |
| Rate of Deleted | 1% | 0% | | | |

Table 6.7.DRH DRH – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 4 | 0 | | | |
| Mean FDA days for submissions that missed goal | 105 | | | | |
| Mean Industry days for submissions that missed goal | 75 | | | | |

Section 7 510(k) Annual General Metrics

510(k) Annual Metrics and Goals will be reported in the Annual Report.

Section 8 Annual Metrics for De Novo Requests

Annual Metrics for De Novo Requests – Center Level

Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of <i>De Novo</i> Requests Received | 46 | | | | |
| Number of <i>De Novo</i> Requests with Decision | 20 | | | | |
| Number of <i>De Novo</i> Requests with Decision Pending | 26 | | | | |
| Average Number of Days to Decision | 103 | | | | |

Section 9 Pre-Submissions

Pre-Submissions – Center Level

Table 9.1 CDRH – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number of all qualified Pre-Submissions received | 1781 | 451 | | | |
| Number requesting a meeting or teleconference | 973 | 260 | | | |
| Number with meetings or teleconferences held | 960 | 52 | | | |
| Average days to meeting | 59 | 46 | | | |
| 20 th Percentile days to meeting | 38 | 30 | | | |
| 40 th Percentile days to meeting | 55 | 45 | | | |
| 60 th Percentile days to meeting | 66 | 53 | | | |
| 80 th Percentile days to meeting | 77 | 60 | | | |
| Maximum days to meeting | 183 | 76 | | | |

Pre-Submissions – Office Level

Table 9.1.ODE ODE – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number of all qualified Pre-Submissions received | 983 | 292 | | | |
| Number requesting a meeting or teleconference | 613 | 192 | | | |
| Number with meetings or teleconferences held | 451 | 32 | | | |
| Average days to meeting | 62 | 47 | | | |
| 20 th Percentile days to meeting | 40 | 36 | | | |
| 40 th Percentile days to meeting | 57 | 49 | | | |
| 60 th Percentile days to meeting | 68 | 54 | | | |
| 80 th Percentile days to meeting | 79 | 60 | | | |
| Maximum days to meeting | 183 | 72 | | | |

Table 9.1.OIR OIR – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 798 | 159 | | | |
| Number requesting a meeting or teleconference | 360 | 68 | | | |
| Number with meetings or teleconferences held | 299 | 20 | | | |
| Average days to meeting | 55 | 43 | | | |
| 20 th Percentile days to meeting | 37 | 26 | | | |
| 40 th Percentile days to meeting | 53 | 41 | | | |
| 60 th Percentile days to meeting | 63 | 51 | | | |
| 80 th Percentile days to meeting | 71 | 63 | | | |
| Maximum days to meeting | 138 | 76 | | | |

Pre-Submissions – Division Level

Table 9.1.DAGRID DAGRID – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number of all qualified Pre-Submissions received | 156 | 51 | | | |
| Number requesting a meeting or teleconference | 82 | 27 | | | |
| Number with meetings or teleconferences held | 59 | 6 | | | |
| Average days to meeting | 69 | 38 | | | |
| 20 th Percentile days to meeting | 52 | 29 | | | |
| 40 th Percentile days to meeting | 66 | 37 | | | |
| 60 th Percentile days to meeting | 75 | 45 | | | |
| 80 th Percentile days to meeting | 85 | 53 | | | |
| Maximum days to meeting | 121 | 55 | | | |

Table 9.1.DCD DCD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 308 | 92 | | | |
| Number requesting a meeting or teleconference | 215 | 66 | | | |
| Number with meetings or teleconferences held | 173 | 17 | | | |
| Average days to meeting | 56 | 47 | | | |
| 20 th Percentile days to meeting | 35 | 37 | | | |
| 40 th Percentile days to meeting | 49 | 45 | | | |
| 60 th Percentile days to meeting | 61 | 52 | | | |
| 80 th Percentile days to meeting | 74 | 58 | | | |
| Maximum days to meeting | 134 | 68 | | | |

Table 9.1.DNPMD DNPMD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 79 | 25 | | | |
| Number requesting a meeting or teleconference | 51 | 17 | | | |
| Number with meetings or teleconferences held | 31 | 1 | | | |
| Average days to meeting | 71 | 59 | | | |
| 20 th Percentile days to meeting | 47 | 59 | | | |
| 40 th Percentile days to meeting | 64 | 59 | | | |
| 60 th Percentile days to meeting | 77 | 59 | | | |
| 80 th Percentile days to meeting | 91 | 59 | | | |
| Maximum days to meeting | 163 | 59 | | | |

Table 9.1.DOD DOD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 98 | 33 | | | |
| Number requesting a meeting or teleconference | 61 | 25 | | | |
| Number with meetings or teleconferences held | 37 | 3 | | | |
| Average days to meeting | 61 | 59 | | | |
| 20 th Percentile days to meeting | 45 | 52 | | | |
| 40 th Percentile days to meeting | 58 | 57 | | | |
| 60 th Percentile days to meeting | 69 | 62 | | | |
| 80 th Percentile days to meeting | 80 | 67 | | | |
| Maximum days to meeting | 129 | 72 | | | |

Table 9.1.DOED DOED – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 87 | 21 | | | |
| Number requesting a meeting or teleconference | 49 | 17 | | | |
| Number with meetings or teleconferences held | 35 | 3 | | | |
| Average days to meeting | 66 | 45 | | | |
| 20 th Percentile days to meeting | 53 | 30 | | | |
| 40 th Percentile days to meeting | 64 | 45 | | | |
| 60 th Percentile days to meeting | 70 | 55 | | | |
| 80 th Percentile days to meeting | 83 | 60 | | | |
| Maximum days to meeting | 118 | 66 | | | |

Table 9.1.DRGUD DRGUD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 131 | 34 | | | |
| Number requesting a meeting or teleconference | 76 | 19 | | | |
| Number with meetings or teleconferences held | 60 | 2 | | | |
| Average days to meeting | 60 | 56 | | | |
| 20 th Percentile days to meeting | 48 | 53 | | | |
| 40 th Percentile days to meeting | 61 | 55 | | | |
| 60 th Percentile days to meeting | 68 | 57 | | | |
| 80 th Percentile days to meeting | 72 | 59 | | | |
| Maximum days to meeting | 133 | 61 | | | |

Table 9.1.DSD DSD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 124 | 36 | | | |
| Number requesting a meeting or teleconference | 79 | 21 | | | |
| Number with meetings or teleconferences held | 56 | 0 | | | |
| Average days to meeting | 61 | n/a | | | |
| 20 th Percentile days to meeting | 37 | n/a | | | |
| 40 th Percentile days to meeting | 63 | n/a | | | |
| 60 th Percentile days to meeting | 71 | n/a | | | |
| 80 th Percentile days to meeting | 83 | n/a | | | |
| Maximum days to meeting | 183 | n/a | | | |

Table 9.1.DCTD DCTD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 219 | 30 | | | |
| Number requesting a meeting or teleconference | 107 | 11 | | | |
| Number with meetings or teleconferences held | 91 | 5 | | | |
| Average days to meeting | 51 | 39 | | | |
| 20 th Percentile days to meeting | 36 | 30 | | | |
| 40 th Percentile days to meeting | 49 | 35 | | | |
| 60 th Percentile days to meeting | 59 | 41 | | | |
| 80 th Percentile days to meeting | 68 | 46 | | | |
| Maximum days to meeting | 90 | 51 | | | |

Table 9.1.DIHD DIHD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 275 | 67 | | | |
| Number requesting a meeting or teleconference | 149 | 36 | | | |
| Number with meetings or teleconferences held | 124 | 11 | | | |
| Average days to meeting | 62 | 47 | | | |
| 20 th Percentile days to meeting | 43 | 20 | | | |
| 40 th Percentile days to meeting | 58 | 52 | | | |
| 60 th Percentile days to meeting | 69 | 63 | | | |
| 80 th Percentile days to meeting | 83 | 70 | | | |
| Maximum days to meeting | 138 | 76 | | | |

Table 9.1.DMD DMD – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 234 | 53 | | | |
| Number requesting a meeting or teleconference | 59 | 14 | | | |
| Number with meetings or teleconferences held | 49 | 1 | | | |
| Average days to meeting | 53 | 56 | | | |
| 20 th Percentile days to meeting | 42 | 56 | | | |
| 40 th Percentile days to meeting | 51 | 56 | | | |
| 60 th Percentile days to meeting | 61 | 56 | | | |
| 80 th Percentile days to meeting | 67 | 56 | | | |
| Maximum days to meeting | 81 | 56 | | | |

Table 9.1.DRH DRH – Pre-Submissions Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of all qualified Pre-Submissions received | 70 | 9 | | | |
| Number requesting a meeting or teleconference | 46 | 7 | | | |
| Number with meetings or teleconferences held | 35 | 3 | | | |
| Average days to meeting | 45 | 33 | | | |
| 20 th Percentile days to meeting | 31 | 22 | | | |
| 40 th Percentile days to meeting | 42 | 35 | | | |
| 60 th Percentile days to meeting | 56 | 43 | | | |
| 80 th Percentile days to meeting | 63 | 46 | | | |
| Maximum days to meeting | 71 | 48 | | | |

Section 10 CLIA Waiver Annual Metrics

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

Section 11 Investigational Device Exemptions (IDEs)

IDEs – Center Level

Table 11.1 CDRH - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 66 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

IDEs – Office Level

Table 11.1.ODE ODE - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 47 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.OIR OIR - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 19 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

IDEs – Division Level

Table 11.1.DAGRID DAGRID - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 1 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | n/a | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | n/a | | | |

Table 11.1.DCD DCD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 12 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DNPMD DNPMD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 11 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DOD DOD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 3 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DOED DOED - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 8 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DRGUD DRGUD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 8 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DSD DSD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 4 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DCTD DCTD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 8 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DIHD DIHD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 7 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | 1 | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | 0 | | | |

Table 11.1.DMD DMD - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 0 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | n/a | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | n/a | | | |

Table 11.1.DRH DRH - IDE Performance Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of IDEs received | n/a | 4 | | | |
| Average number of cycles to approval to or conditional approval of the IDE | n/a | n/a | | | |
| Average number of amendments prior to approval or conditional approval of the IDE | n/a | n/a | | | |

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

Table 1.1 and Tables 1.1.x PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions

| # | Measure | Description |
|---|--|--|
| 1 | Number Received | Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above). |
| 2 | Closed before RTA action | Number Received (line 1) that were closed with a final decision before RTA action. |
| 3 | Number with accepted RTA review | Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer. |
| 4 | Number without RTA Review and > 15 Days since Date Received | Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved. |
| 5 | Number without RTA Review and <= 15 Days since Date Received | Number Received (line 1) that are still in the first RTA review cycle. |
| 6 | Number Not Accepted for Filing Review | Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle. |
| 7 | Rate of submissions not accepted for filing review | Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6). |

Table 1.2 and Tables 1.2.x PMA Original and Panel Track Supplements – Filing Review Decision - Definitions

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number Received | Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above). |
| 2 | Number Accepted [#] | Number Received (line 1) that got "RTA Accepted" (RTAA), RTAX, or RTAN decision in the first RTA review cycle entered by reviewer. |
| 3 | Number with completed RTF | Number of submissions with the first RTF review completed in this fiscal year. |
| 4 | Number Not Filed | Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review. |
| 5 | Rate of submissions Not Filed | Number Not Filed (line 4) divided by Number with completed RTF (line 3). |

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013

Table 1.3 and Tables 1.3.x**PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

| # | Measure | Description |
|---|---|---|
| 1 | Eligible for SI | Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year. |
| 2 | SI within 90 FDA days | Number of submissions with SI action within 90 FDA days. |
| 3 | SI over 90 FDA days | Number of submissions with SI action taken in more than 90 FDA days. |
| 4 | SI pending within 90 FDA days | Number of submissions that are under review for not more than 90 FDA days and with no SI. |
| 5 | SI pending over 90 FDA days | Number of submissions that are under review for more than 90 FDA days with no SI. |
| 6 | Closed without SI | Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn). |
| 7 | Current SI Performance Percent within 90 FDA days | Number of submissions with SI within 90 FDA days (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5). |

Table 1.4 and Tables 1.4.x**PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of Substantive Interactions | Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI. |
| 2 | Average number of FDA days to Substantive Interaction | Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1). |
| 3 | 20 th Percentile FDA days to Substantive Interaction | 20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 4 | 40 th Percentile FDA days to Substantive Interaction | 40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 5 | 60 th Percentile FDA days to Substantive Interaction | 60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 6 | 80 th Percentile FDA days to Substantive Interaction | 80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 7 | Maximum FDA days to Substantive Interaction | Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1). |

Tables 1.5 and Tables 1.5.x**PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of PMAs filed | Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested. |
| 2 | Non-MDUFA III Decisions | Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMa). |
| 3 | MDUFA III Decisions | Submissions filed (line 1) and closed with a MDUFA III decision. |
| 4 | MDUFA III Decisions within 180 FDA Days | Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition. |
| 5 | PMAs pending MDUFA III Decision | Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision. |
| 6 | PMAs pending MDUFA III Decision over 180 FDA days | Number of submissions pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These submissions already failed the MDUFA III review goal. |
| 7 | Current Performance Percent within 180 FDA Days | Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 1.6 and Tables 1.6.x**PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of PMAs filed | Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested. |
| 2 | Non-MDUFA III Decisions | Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMa). |
| 3 | MDUFA III Decisions | Submissions filed (line 1) and closed with a MDUFA III decision. |
| 4 | MDUFA III Decisions within 320 FDA Days | Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition. |
| 5 | PMAs pending MDUFA III Decision | Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision. |
| 6 | PMAs pending MDUFA III Decision over 320 FDA days | Number of submissions pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These submissions already failed the MDUFA III review goal. |
| 7 | Current Performance Percent within 320 FDA Days | Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 1.7 and Tables 1.7.x**PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions**

| # | Measure | Description |
|---|--------------------------------|---|
| 1 | Number with MDUFA III Decision | Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date. |
| | Days to MDUFA Decision | Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

Table 1.8 and Tables 1.8.x**PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions**

| # | Measure | Description |
|---|--------------------------------|---|
| 1 | Number with MDUFA III Decision | Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date. |
| | Days to MDUFA Decision | Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

Table 1.9 and Tables 1.9.x**PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

| # | Measure | Description |
|---|----------------------------|---|
| 1 | Number Filed | Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested. |
| 2 | Number with MDUFA decision | Number submissions filed (line 1) that also had a MDUFA decision. |
| 3 | Number of Withdrawals | Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn). |
| 4 | Number of Not Approvable | Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable). |
| 5 | Rate of Withdrawals | Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2). |
| 6 | Rate of Not Approvable | Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2). |

Table 1.10 and Tables 1.10.x**PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

| # | Measure | Description |
|---|----------------------------|--|
| 1 | Number Filed | Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested. |
| 2 | Number with MDUFA decision | Number submissions filed (line 1) that also had a MDUFA decision. |
| 3 | Number of Withdrawals | Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn). |
| 4 | Number of Not Approvable | Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable). |
| 5 | Rate of Withdrawals | Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2). |
| 6 | Rate of Not Approvable | Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2). |

Table 1.11 and Tables 1.11.x **PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

| # | Measure | Description |
|---|---|---|
| 1 | Number of submissions that missed the goal | Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days. |
| 2 | Mean FDA days for submissions that missed goal | Mean FDA days for submissions that missed the goal (line 1). |
| 3 | Mean industry days for submissions that missed goal | Mean industry days for submissions that missed the goal (line 1). |

Table 1.12 and Tables 1.12.x **PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of submissions that missed the goal | Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days. |
| 2 | Mean FDA days for submissions that missed goal | Mean FDA days for submissions that missed the goal (line 1). |
| 3 | Mean industry days for submissions that missed goal | Mean industry days for submissions that missed the goal (line 1). |

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals - Definitions

| # | Measure | Description |
|---|---|---|
| 1 | Eligible for SI | Number of 180 day PMA supplements received in this fiscal year. See definition of the received cohort above. |
| 2 | SI within 90 FDA days | Number of submissions with an SI action taken within 90 FDA days. |
| 3 | SI over 90 FDA days | Number of submissions with an SI action taken in more than 90 FDA days. |
| 4 | SI pending within 90 FDA days | Submissions that are under review for not more than 90 FDA days and that do not have an SI. |
| 5 | SI pending over 90 FDA days | Submissions that are under review for more than 90 FDA days and that do not have an SI. |
| 6 | Closed without SI | Number of submissions that are closed with a MDUFA or NON-MDUFA decision but without an SI. |
| 7 | Current SI Performance Percent within 90 FDA days | Number of submissions with SI within 90 FDA days (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5). |

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals - Definitions

| # | Measure | Description |
|---|--|--|
| 1 | Supplements filed | Number of 180 day PMA supplements received in this fiscal year. |
| 2 | Non-MDUFA III Decisions | Supplements received (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa). |
| 3 | MDUFA III Decisions | Supplements received (line 1) and closed with a MDUFA III decision. |
| 4 | MDUFA III Decisions within 180 FDA Days | Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition. |
| 5 | Supplements pending MDUFA III Decision | Number of supplements received (line 1) that do not have a MDUFA III decision or a final decision. |
| 6 | Supplements pending MDUFA III Decision over 180 FDA days | Number of supplements pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These supplements already failed the MDUFA III review goal. |
| 7 | Current Performance Percent within 180 FDA Days | Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6). |

Table 2.3 and Tables 2.3.x PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable - Definitions

| # | Measure | Description |
|---|----------------------------|--|
| 1 | Number Received | Number of PMA 180 Day Supplements received in this fiscal year. |
| 2 | Number with MDUFA decision | Number supplements received (line 1) and closed with a MDUFA decision. |
| 3 | Number of Not Approvable | Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable). |
| 4 | Rate of Not Approvable | Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2). |

Table 2.4 and Tables 2.4.x**PMA 180 Day Supplements Performance Metrics –
Submissions Missing Performance Goals - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of submissions that missed the goal | Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA III decision exceeding number of goal days. |
| 2 | Mean FDA days for submissions that missed goal | Mean FDA days for supplements that missed the goal (line 1). |
| 3 | Mean industry days for submissions that missed goal | Mean industry days for supplements that missed the goal (line 1). |

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Supplements received | Number of Real Time PMA supplements that were received in this fiscal year. See the Received cohort definition above. |
| 2 | Non-MDUFA III Decisions | Supplements received in this fiscal year (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA). |
| 3 | MDUFA III Decisions | Supplements received in this fiscal year (line 1) and closed with a MDUFA III decision. |
| 4 | MDUFA III Decisions within 90 FDA Days | Submissions with MDUFA III decisions (line 3) made in less than or equal to 90 FDA days. |
| 5 | Supplements pending MDUFA III Decision | Number of supplements received in this fiscal year (line 1) that do not have a MDUFA III decision and are not closed with a final decision. |
| 6 | Supplements pending MDUFA III Decision over 90 FDA days | Number of supplements pending MDUFA III Decision (line 5) for more than 90 FDA Days. These supplements already failed the MDUFA III review goal. |
| 7 | Current Performance Percent within 90 FDA Days | Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6). |

Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable - Definitions

| # | Measure | Description |
|---|----------------------------|--|
| 1 | Number Received | Number of PMA Real Time Supplements received in this fiscal year. |
| 2 | Number with MDUFA decision | Number supplements received (line 1) and closed with a MDUFA decision. |
| 3 | Number of Not Approvable | Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable). |
| 4 | Rate of Not Approvable | Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2). |

Table 3.3 and Tables 3.3.x Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals - Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Number of submissions that missed the goal | Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days. |
| 2 | Mean FDA days for submissions that missed goal | Mean FDA days for supplements that missed the goal (line 1). |
| 3 | Mean industry days for submissions that missed goal | Mean industry days for supplements that missed the goal (line 1). |

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

| # | Measure | Description |
|----|---|--|
| 1 | Premarket Report Submissions | Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year. |
| 2 | Original PMAs (Panel) – Priority | Number of PMA Original submissions with Panel review requested and Priority flag set to "Yes", received in this fiscal year. |
| 3 | Original PMAs (No Panel) – Priority | Number of PMA Original submissions with no Panel review requested and Priority flag set to "Yes", received in this fiscal year. |
| 4 | Original PMAs (Panel) – Non-Priority | Number of PMA Original submissions with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year. |
| 5 | Original PMAs (No Panel) – Non-Priority | Number of PMA Original submissions with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year. |
| 6 | Panel Track Supplements (Panel) – Priority | Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "Yes", received in this fiscal year. |
| 7 | Panel Track Supplements (No Panel) – Priority | Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "Yes", received in this fiscal year. |
| 8 | Panel Track Supplements (Panel) – Non-Priority | Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year. |
| 9 | Panel Track Supplements (No Panel) – Non-Priority | Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year. |
| 10 | PMA Modules | Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year. |
| 11 | 180-Day Supplements | Number of PMA 180-Day supplements received in this fiscal year. |
| 12 | Real-Time Supplements | Number of PMA Real-Time supplements received in this fiscal year. |

Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Number Filed | Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year. |
| 2 | Number with a decision (MDUFA or Non-MDUFA) | Number of submissions filed in this fiscal year (line 1) that were closed with either MDUFA or non-MDUFA decision. |
| 3 | % of FY closed | Number with a decision (line 2) divided by Number Filed (line 1). |

Table 5.3 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision - Definitions

| # | Measure | Description |
|---|--|--|
| 1 | Number with MDUFA decision | Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision. |
| 2 | Number with MDUFA decision after trimming the upper and lower 5% | Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA III decision and 5% of submissions with the highest number of Total Days to MDUFA III decision. |
| 3 | Three-year Rolling Average Total Time to MDUFA decision | Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY20111 and FY2012 Total Time to MDUFA II (two) decision will be used. |

Section 6 510(k) MDUFA III Performance

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision - Definitions

| # | Measure | Description |
|---|--|--|
| 1 | Number Received | Number of 510(k) submissions received in this fiscal year. See definition for received cohort above. Third party reviews shall be excluded from this table. |
| 2 | Closed before RTA action | Number Received (line 1) that were closed with a final decision before RTA action. |
| 3 | Number Accepted | Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer. |
| 4 | RTA Review not done and > 15 days since Date Received | Number Received (line 1) that got "Did not perform RTA" (RTAN or RTAS) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved. |
| 5 | RTA Review not done and <= 15 days since Date Received | Number Received (line 1) that are still in the first RTA review cycle. |
| 6 | Number Not Accepted | Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" decision in the first RTA review cycle. |
| 7 | Rate of submissions not accepted | Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6). |

Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goals - Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Eligible for SI | Number of 510(k) submissions with RTA review accepted in this fiscal year (RTAA, RTAX, RTAN, or RTAS.). Third party 510(k) submissions are excluded from SI performance report. |
| 2 | 510(k) withdrawn or deleted prior to SI | Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made before or on the cutoff date and before any SI action: WD, DD, DE, HD, K4, NR, RC, RD . |
| 3 | SI within 60 FDA days | Number of submissions with SI action within 60 FDA days. |
| 4 | SI over 60 FDA days | Number of submissions with SI action taken in more than 60 FDA days. |
| 5 | SI pending within 60 FDA days | Submissions that are under review for not more than 60 FDA days and that do not have an SI. |
| 6 | SI pending over 60 FDA days | Submissions that are under review over 60 FDA days and that do not have an SI. |
| 7 | 510(k)s NSE without SI | Number of 510(k) submissions that are closed with an NSE decision (or with an AN, DN, or ON decision where Date Received does not equal Date Final Decision) and did not have an SI. |
| 8 | Current SI Performance Percent within 60 FDA days | Number of submissions with SI within 60 FDA days (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7). |

Table 6.3 and Tables 6.3.x**510(k) Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of Substantive Interactions | Number of 510(k) submissions accepted in this fiscal year that had an SI. Third party 510(k) submissions shall be excluded from this report. |
| 2 | Average number of FDA days to Substantive Interaction | Average number of FDA days across all 510(k) submissions with SI (line 1). |
| 3 | 20 th Percentile FDA days to Substantive Interaction | 20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 4 | 40 th Percentile FDA days to Substantive Interaction | 40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 5 | 60 th Percentile FDA days to Substantive Interaction | 60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 6 | 80 th Percentile FDA days to Substantive Interaction | 80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 7 | Maximum FDA days to Substantive Interaction | Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1). |

Tables 6.4 and Tables 6.4.x**510(k) MDUFA Decision Performance Goals - Definitions**

| # | Measure | Description |
|---|--|--|
| 1 | 510(k)s accepted | Number of 510(k) submissions accepted in this fiscal year. Third party 510(k) shall also be included into this report. |
| 2 | Non-MDUFA III Decisions | Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not SE or NSE). |
| 3 | MDUFA III Decisions (SE/NSE) | Number of submissions accepted (line 1) and closed with a MDUFA III decision (SE or NSE). |
| 4 | MDUFA III Decisions within 90 FDA Days | Number of submissions with MDUFA III decisions (line 3) made within 90 FDA days. |
| 5 | 510(k)s pending MDUFA III Decision | Number of submissions accepted (line 1) and still under review. |
| 6 | 510(k) pending MDUFA III Decision over 90 FDA days | Number of submissions pending MDUFA III Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA III review goal. |
| 7 | Current Performance Percent within 90 FDA Days | Number of submissions with MDUFA III Decisions within 90 FDA Days (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 6.5 and Tables 6.5.x**510(k) Time to MDUFA Decision - Definitions**

| # | Measure | Description |
|---|--------------------------------|---|
| 1 | Average review cycles | Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2). |
| 2 | Number with MDUFA III Decision | Number of submissions accepted in this fiscal year that had a MDUFA decision. |
| | Days to MDUFA Decision | Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

Table 6.6 and Tables 6.6.x**510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions - Definitions**

| # | Measure | Description |
|----|----------------------------|--|
| 1 | Number Accepted | Number of 510(k) submissions accepted in this fiscal year. See definition for Accepted cohort above. |
| 2 | Number with MDUFA decision | Number submissions accepted (line 1) that also had a MDUFA decision. |
| 3 | Number of SE decisions | Number of submissions accepted (line 1) that had an SE MDUFA decision. |
| 4 | Number of NSE decisions | Number of submissions accepted (line 1) that had an NSE MDUFA decision. |
| 5 | Number of Withdrawals | Number of submissions accepted (line 1) and closed with Withdrawal (WD) final decision. |
| 6 | Number deleted | Number of submissions accepted (line 1) and closed with Delete (DE) final decision. |
| 7 | Rate of SE decisions | Number of SE decisions (line 3) divided by Number with MDUFA decision (line 2). |
| 8 | Rate of NSE decisions | Number of NSE decisions (line 4) divided by Number with MDUFA decision (line 2). |
| 9 | Rate of Withdrawals | Number of Withdrawals (line 5) divided by Number Received (line 1). |
| 10 | Rate of Deleted | Number of Deleted (line 6) divided by Number Received (line 1). |

Table 6.7 and Tables 6.7.x**510(k) Performance Metrics – Submissions Missing Performance Goals - Definitions**

| # | Measure | Description |
|---|---|---|
| 1 | Number of submissions that missed the goal | Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days. Third Party 510(k) submissions shall also be included into this report. |
| 2 | Mean FDA days for submissions that missed goal | Mean FDA days for submissions that missed the goal (line 1). |
| 3 | Mean industry days for submissions that missed goal | Mean industry days for submissions that missed the goal (line 1). |

Section 7 510(k) Annual General Metrics

Table 7.1 CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type - Definitions

| # | Measure | Description |
|---|---|---|
| 1 | Number Accepted | Total number of 510(k) submissions accepted in this fiscal year. Third party 510(k) submissions shall also be included into this count. |
| 2 | Number of Traditional submissions | Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year. |
| 3 | Number of Special submissions | Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year. |
| 4 | Number of Abbreviated submissions | Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year. |
| 5 | Average number of days to Accept / Refuse to Accept | Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions. |
| 6 | Number of Third Party submissions | Number of Third Party 510(k) submissions received in this fiscal year. |

Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal - Definitions

| # | Measure | Description |
|---|--|---|
| 1 | Number Accepted | Total number of 510(k) submissions accepted in this fiscal year. Third-party 510(k) submissions shall also be included into this report. |
| 2 | Currently Under Review | Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet). |
| 3 | Number with Non-MDUFA decision | Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision. |
| 4 | Number with MDUFA III Decision | Total number of 510(k) submissions accepted (line 1) that had a MDUFA III decision. |
| 5 | Percent of cohort closed | Number with MDUFA decision (line 4) divided by the total of Number Under Review (line 2) and Number with MDUFA Decision (line 4). |
| 6 | Number with MDUFA III decision after trimming the upper and lower 2% | Number of 510(k) submissions with MDUFA III Decision (line 4) excluding 2% of submissions with the lowest number of Total Days to MDUFA III decision and 2% of submissions with the highest number of Total Days to MDUFA III decision. |
| 7 | Average Total Time to MDUFA III decision | Average Total Time (FDA and Industry) to MDUFA decision. If the cohort is not closed (less than 99% of 510(k) submissions have a decision) "N/A" shall be displayed instead. |

Section 8 Annual Metrics for De Novo Requests

Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests - Definitions

| # | Measure | Description |
|---|---|---|
| 1 | Number of <i>De Novo</i> Requests Received | Total number of <i>de novo</i> requests received in this fiscal year as of the report cutoff date. |
| 2 | Number of <i>De Novo</i> Requests with Decision | Number of <i>de novo</i> requests received (line 1) which also have a final decision (AN, DN, or ON) as of the report cutoff date. |
| 3 | Number of <i>De Novo</i> Requests with Decision Pending | Number <i>de novo</i> requests received (line 1) which do not have a final decision (AN, DN, or ON) as of the report cutoff date. |
| 4 | Average Number of Days to Decision | Average total number of days to decision (days between <i>De Novo</i> Date Received and <i>De Novo</i> Decision Date) for <i>de novo</i> requests with Decision (line 2). |

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Submissions Performance Metrics - Definitions

| # | Measure | Description |
|---|--|---|
| 1 | Number of all qualified Pre-Submissions received | Number of all qualified Pre-Submissions received. This include those with a type="pre-sub" either with a meeting request or written feedback requested in the fiscal year. |
| 2 | Number requesting a meeting or teleconference | Number of qualified Pre-submission received (line 1) with the Sub-Type of "Pre-Sub Meeting Request". |
| 3 | Number with meetings or teleconferences held | Number requesting a meeting or teleconference (line 2) with Actual Meeting Date populated with a value prior to the cutoff date. |
| 4 | Days to meeting | Table shall show average days from Date FDA Initial Clock Start to Actual Meeting Date as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting days, Industry days, and Total days. The calculation includes meetings where the Actual Meeting Date is greater than the Date FDA Initial Clock Start and the Actual Meeting Date is prior to as of the cutoff date. |

Section 10 CLIA Waiver Annual Metrics

Table 10.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

| # | Measure | Description |
|---|---|---|
| 1 | Eligible for SI | Number of CLIA Waiver by Applications that were filed in this fiscal year |
| 2 | Deleted or withdrawn prior to SI | Number of submissions with MDUFA Decision WTDR within 90 FDA days |
| 3 | SI within 90 FDA days | Number of submissions with SI action within 90 FDA days |
| 4 | SI over 90 FDA days | Number of submissions with SI action taken in more than 90 FDA days |
| 5 | SI pending within 90 FDA days | Number of submissions that are under review for not more than 90 FDA days and with no SI |
| 6 | SI pending over 90 FDA days | Number of submissions that are under review for more than 90 FDA days with no SI |
| 7 | Denial without SI | Number of submissions closed with a Denial decision and that did not have an SI prior |
| 8 | Current SI Performance Percent within 90 FDA days | Number of submissions with SI within 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1) |

Table 10.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Number of Substantive Interactions | Number of CLIA Waiver by Applications filed in this fiscal year that had an SI |
| 2 | Average number of FDA days to Substantive Interaction | Average number of FDA days across all CLIA Waivers with SI (line 1). |
| 3 | 20 th Percentile FDA days to Substantive Interaction | 20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 4 | 40 th Percentile FDA days to Substantive Interaction | 40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 5 | 60 th Percentile FDA days to Substantive Interaction | 60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 6 | 80 th Percentile FDA days to Substantive Interaction | 80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 7 | Maximum FDA days to Substantive Interaction | Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1). |

Table 10.3 CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals) – Definitions

| # | Measure | Description |
|---|---|---|
| 1 | CLIA Waiver Applications accepted | Number of CLIA Waiver by Applications that were filed in this fiscal year |
| 2 | Non-MDUFA III Decisions | Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn) |
| 3 | MDUFA III Decisions | Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn) |
| 4 | MDUFA III Decisions within 180 FDA Days | Number of submissions with MDUFA III decisions (line 3) made within 180 FDA days |
| 5 | CLIA Waiver Applications pending MDUFA III Decision | Number of submissions accepted (line 1) and still under review |
| 6 | CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days | Number of submissions pending MDUFA III Decision (line5) for more than 180 FDA days. These submissions already failed the MDUFA III Decision goal. |
| 7 | Current Performance Percent within 180 FDA Days | Number of submissions with MDUFA III Decisions within 180 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6) |

Table 10.4 CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals) – Definitions

| # | Measure | Description |
|---|---|---|
| 1 | CLIA Waiver Applications accepted | Number of CLIA Waiver by Applications that were filed in this fiscal year |
| 2 | Non-MDUFA III Decisions | Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn) |
| 3 | MDUFA III Decisions | Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn) |
| 4 | MDUFA III Decisions within 330 FDA Days | Number of submissions with MDUFA III decisions (line 3) made within 330 FDA days |
| 5 | CLIA Waiver Applications pending MDUFA III Decision | Number of submissions accepted (line 1) and still under review |
| 6 | CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days | Number of submissions pending MDUFA III Decision (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal. |
| 7 | Current Performance Percent within 330 FDA Days | Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6) |

Table 10.5 CLIA Waiver (without Panel Review) Time to MDUFA Decision – Definitions

| # | Measure | Description |
|---|----------------------------|---|
| 1 | Number with MDUFA decision | Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn) |
| | Days to MDUFA Decision | Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

Table 10.6 **CLIA Waiver (with Panel Review) Time to MDUFA Decision - Definitions**

| # | Measure | Description |
|---|----------------------------|---|
| 1 | Number with MDUFA decision | Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn) |
| | Days to MDUFA Decision | Table shall show Average Days to MDUFA III decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

Section 11 IDE Performance Metrics

Table 11.1 IDE Performance Metrics

| # | Measure | Description |
|---|---|--|
| 1 | Number of IDEs received | Number of IDEs received in the fiscal year. |
| 2 | Average number of cycles to approval or conditional approval of the IDE | The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE. |
| 3 | Average number of amendments prior to approval or conditional approval of the IDE | The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter. |

**Quarterly Update on
Medical Device Performance Goals
----MDUFA III CBER Performance Data ----
Action through 31 December 2013**

Section 1 PMA Original and Panel Track Supplements - Center Level

Table 1.1 CBER – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number Received | 1 | 1 | | | |
| Closed before RTA action | 0 | 0 | | | |
| Number Accepted | 1 | 1 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 0 | | | |
| Number Not Accepted for Filing Review | 0 | 0 | | | |
| Rate of submissions not accepted for filing review | 0.0% | 0.0% | | | |
| Completed RTF | 0 | 0 | | | |
| Number Not Filed | 0 | 1 | | | |
| Rate of submissions Not Filed | 0.0% | 100.0% | | | |

Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA days | 85% SI within 90 FDA days | 95% SI within 90 FDA days | 95% SI within 90 FDA days |
| Eligible for SI | 1 | 1 | | | |
| SI within 90 FDA days | 0 | 0 | | | |
| SI over 90 FDA days | 1 | 0 | | | |
| SI pending within 90 FDA days | 0 | 1 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 0 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 0.0% | 0.0% | | | |

Table 1.3 CBER – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of Substantive Interactions | 1 | 0 | | | |
| Average number of FDA days to Substantive Interaction | 101 | 0 | | | |
| 20th Percentile FDA days to Substantive Interaction | 101 | 0 | | | |

| | | | | | |
|---|-----|---|--|--|--|
| 40th Percentile FDA days to Substantive Interaction | 101 | 0 | | | |
| 60th Percentile FDA days to Substantive Interaction | 101 | 0 | | | |
| 80th Percentile FDA days to Substantive Interaction | 101 | 0 | | | |
| Maximum FDA days to Substantive Interaction | 101 | 0 | | | |

Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 70% within 180 FDA days | 80% within 180 FDA days | 80% within 180 FDA days | 90% within 180 FDA days | 90% within 180 FDA days |
| Number of PMAs filed | 0 | 0 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 0 | 1 | | | |
| PMAs pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 0.0% | 0.0% | | | |

Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 50% within 320 FDA days | 70% within 320 FDA days | 80% within 320 FDA days | 80% within 320 FDA days | 90% within 320 FDA days |
| Number of PMAs filed | 1 | 0 | | | |
| Non-MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions within 320 FDA Days | 0 | 0 | | | |
| PMAs pending MDUFA III Decision | 1 | 0 | | | |
| PMAs pending MDUFA III Decision over 320 FDA days | 0 | 0 | | | |
| Current Performance Percent within 320 FDA Days | 0.0% | 0.0% | | | |

Table 1.6 CBER – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--------------------------------|---------|---------|---------|---------|---------|
| Number with MDUFA III decision | 0 | 0 | | | |

| | | | | | |
|---|----------|----------|--|--|--|
| Average FDA days to MDUFA III decision | 0 | 0 | | | |
| 20th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| Maximum FDA days to MDUFA III decision | 0 | 0 | | | |
| Average Industry days to MDUFA III decision | 0 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 0 | 0 | | | |
| Average Total days to MDUFA III decision | 0 | 0 | | | |
| 20th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| Maximum Total days to MDUFA III decision | 0 | 0 | | | |

Table 1.7 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA III decision | 0 | 0 | | | |
| Average FDA days to MDUFA III decision | 0 | 0 | | | |
| 20th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile FDA days to MDUFA III decision | 0 | 0 | | | |
| Maximum FDA days to MDUFA III decision | 0 | 0 | | | |

| | | | | | |
|---|----------|----------|--|--|--|
| Average Industry days to MDUFA III decision | 0 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 0 | 0 | | | |
| Average Total days to MDUFA III decision | 0 | 0 | | | |
| 20th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile Total days to MDUFA III decision | 0 | 0 | | | |
| Maximum Total days to MDUFA III decision | 0 | 0 | | | |

**Table 1.8 CBER – PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0.0% | 0.0% | | | |
| Rate of Not Approvable | 0.0% | 0.0% | | | |

Table 1.9 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 1 | 0 | | | |
| Number with MDUFA decision | 0 | 0 | | | |
| Number of Withdrawals | 0 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Withdrawals | 0.0% | 0.0% | | | |
| Rate of Not Approvable | 0.0% | 0.0% | | | |

Table 1.10 CBER – PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | 0 | 0 | | | |
| Mean industry days for submissions that missed goal | 0 | 0 | | | |

Table 1.11 CBER – PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | 0 | 0 | | | |
| Mean industry days for submissions that missed goal | 0 | 0 | | | |

Section 2 PMA 180 Day Supplements - Center Level

Table 2.1 CBER – PMA 180 Day Supplements Substantive Interaction Goals

| Substantive Interaction (SI) Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 65% SI within 90 FDA days | 75% SI within 90 FDA days | 85% SI within 90 FDA days | 95% SI within 90 FDA days | 95% SI within 90 FDA days |
| Eligible for SI | 1 | 0 | | | |
| SI within 90 FDA days | 1 | 0 | | | |
| SI over 90 FDA days | 0 | 0 | | | |
| SI pending within 90 FDA days | 0 | 0 | | | |
| SI pending over 90 FDA days | 0 | 0 | | | |
| Closed without SI | 1 | 0 | | | |
| Current SI Performance Percent within 90 FDA days | 100.0% | 0.0% | | | |

Table 2.2 CBER – PMA 180 Day Supplements MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 85% within 180 FDA days | 90% within 180 FDA days | 90% within 180 FDA days | 95% within 180 FDA days | 95% within 180 FDA days |
| Supplements received | 3 | 0 | | | |
| Non-MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions | 1 | 0 | | | |
| MDUFA III Decisions within 180 FDA Days | 1 | 0 | | | |
| Supplements pending MDUFA III Decision | 1 | 0 | | | |
| Supplements pending MDUFA III Decision over 180 FDA days | 0 | 0 | | | |
| Current Performance Percent within 180 FDA Days | 100.0% | 0.0% | | | |

Table 2.3 CBER – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 3 | 0 | | | |
| Number with MDUFA decision | 1 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0.0% | 0.0% | | | |

Table 2.4 CBER – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | 0 | 0 | | | |
| Mean Industry days for submissions that missed goal | 0 | 0 | | | |

Section 3 PMA Real Time Supplements - Center Level Metrics

Table 3.1 CBER – Real Time PMA Supplements MDUFA Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 90% within 90 FDA days | 90% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| Supplements received | 3 | 1 | | | |
| Non-MDUFA III Decisions | 0 | 0 | | | |
| MDUFA III Decisions | 3 | 0 | | | |
| MDUFA III Decisions within 90 FDA Days | 3 | 0 | | | |
| Supplements pending MDUFA III Decision | 0 | 1 | | | |
| Supplements pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100.0% | 0.0% | | | |

Table 3.2 CBER – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Received | 3 | 1 | | | |
| Number with MDUFA decision | 3 | 0 | | | |
| Number of Not Approvable | 0 | 0 | | | |
| Rate of Not Approvable | 0.0% | 0.0% | | | |

Table 3.3 CBER – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | 0 | 0 | | | |
| Mean Industry days for submissions that missed goal | 0 | 0 | | | |

Section 5 PMA Annual Metrics and Goals

Table 5.1 CBER – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type

| PMA Submissions Received | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Premarket Report Submissions | 0 | 0 | | | |
| Original PMAs (Panel) – Priority | 0 | 0 | | | |
| Original PMAs (No Panel) – Priority | 0 | 0 | | | |
| Original PMAs (Panel) – Non-Priority | 1 | 0 | | | |
| Original PMAs (No Panel) – Non-Priority | 0 | 1 | | | |
| Panel-Tracked Supplements (Panel) – Priority | 0 | 0 | | | |
| Panel-Tracked Supplements (No Panel) – Priority | 0 | 0 | | | |
| Panel-Tracked Supplements (Panel) – Non-Priority | 0 | 0 | | | |
| Panel-Tracked Supplements (No Panel) – Non-Priority | 0 | 0 | | | |
| PMA Modules | 7 | 1 | | | |
| 180-Day Supplements | 3 | 0 | | | |
| Real-Time Supplements | 3 | 1 | | | |

Table 5.2 CBER – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | | | |
| Number with a decision (MDUFA or Non-MDUFA) | 1 | 0 | | | |
| % of FY closed | 0.0% | 0.0% | | | |

Section 6 510(k) Center Level Metrics

Table 6.1 CBER – 510(k) Acceptance Review Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number Received | 59 | 14 | | | |
| Closed before RTA action | 3 | 1 | | | |
| Number Accepted | 46 | 6 | | | |
| Number without a RTA Review and > 15 Days since Date Received | 0 | 0 | | | |
| Number without a RTA Review and <= 15 Days since Date Received | 0 | 4 | | | |
| Number Not Accepted | 10 | 3 | | | |
| Rate of submissions not accepted for review | 21.7% | 21.4% | | | |

Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals

| Substantive Interaction (SI) Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| | 65% SI within 60 FDA days | 75% SI within 60 FDA days | 85% SI within 60 FDA days | 95% SI within 60 FDA days | 95% SI within 60 FDA days |
| Eligible for SI | 46 | 6 | | | |
| SI within 60 FDA days | 40 | 3 | | | |
| SI over 60 FDA days | 6 | 0 | | | |
| SI pending within 60 FDA days | 0 | 2 | | | |
| SI pending over 60 FDA days | 0 | 1 | | | |
| 510(k)s NSE without SI | 0 | 0 | | | |
| Current SI Performance Percent within 60 FDA days | 87.0% | 50.0% | | | |

Table 6.3 CBER – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of Substantive Interactions | 46 | 3 | | | |
| Average number of FDA days to Substantive Interaction | 49 | 33 | | | |
| 20th Percentile FDA days to Substantive Interaction | 29 | 0 | | | |
| 40th Percentile FDA days to Substantive Interaction | 46 | 21 | | | |
| 60th Percentile FDA days to Substantive Interaction | 58 | 21 | | | |
| 80th Percentile FDA days to Substantive Interaction | 60 | 28 | | | |
| Maximum FDA days to Substantive Interaction | 90 | 50 | | | |

Table 6.4 CBER – 510(k) MDUEA Decision Performance Goals

Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals

| Performance Goals: | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 91% within 90 FDA days | 93% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days | 95% within 90 FDA days |
| 510(k)s accepted | 46 | 6 | | | |
| Non-MDUFA III Decisions | 41 | 0 | | | |
| MDUFA III Decisions (SE/NSE) | 26 | 2 | | | |
| MDUFA III Decisions within 90 FDA Days | 26 | 2 | | | |
| 510(k)s pending MDUFA III Decision | 15 | 4 | | | |
| 510(k) pending MDUFA III Decision over 90 FDA days | 0 | 0 | | | |
| Current Performance Percent within 90 FDA Days | 100.0% | 100.0% | | | |

Table 6.5 CBER – 510(k) Time to MDUFA Decision

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Average review cycles | 1.46 | 1.00 | | | |
| Number with MDUFA III decision | 26 | 2 | | | |
| Average FDA days to MDUFA III decision | 65 | 25 | | | |
| 20th Percentile FDA days to MDUFA III decision | 28 | 0 | | | |
| 40th Percentile FDA days to MDUFA III decision | 49 | 0 | | | |
| 60th Percentile FDA days to MDUFA III decision | 85 | 21 | | | |
| 80th Percentile FDA days to MDUFA III decision | 88 | 21 | | | |
| Maximum FDA days to MDUFA III decision | 90 | 28 | | | |
| Average Industry days to MDUFA III decision | 43 | 0 | | | |
| 20th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 40th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 60th Percentile Industry days to MDUFA III decision | 0 | 0 | | | |
| 80th Percentile Industry days to MDUFA III decision | 83 | 0 | | | |
| Maximum Industry days to MDUFA III decision | 222 | 0 | | | |
| Average Total days to MDUFA III decision | 108 | 25 | | | |
| 20th Percentile Total days to MDUFA III decision | 28 | 0 | | | |
| 40th Percentile Total days to MDUFA III decision | 49 | 0 | | | |
| 60th Percentile Total days to MDUFA III decision | 90 | 21 | | | |

| | | | | | |
|--|-----|----|--|--|--|
| 80th Percentile Total days to MDUFA III decision | 142 | 21 | | | |
| Maximum Total days to MDUFA III decision | 307 | 28 | | | |

Table 6.6 CBER – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|----------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 46 | 6 | | | |
| Number with MDUFA decision | 26 | 2 | | | |
| Number of SE decisions | 24 | 2 | | | |
| Number of NSE decisions | 2 | 0 | | | |
| Number of Withdrawals | 5 | 1 | | | |
| Number deleted | 0 | 0 | | | |
| Rate of SE decisions | 52.2% | 33.3% | | | |
| Rate of NSE decisions | 4.3% | 0.0% | | | |
| Rate of Withdrawals | 10.9% | 16.7% | | | |
| Rate of Deleted | 0.0% | 0.0% | | | |

Table 6.7 CBER – 510(k) Performance Metrics – Submissions Missing Performance Goals

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of submissions that missed the goal | 0 | 0 | | | |
| Mean FDA days for submissions that missed goal | 0 | 0 | | | |
| Mean industry days for submissions that missed goal | 0 | 0 | | | |

Section 7 510(k) Annual General Metrics

Table 7.1 CBER – 510(k) Annual General Metrics – 510(k)s Received by Type

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|-----------------------------------|---------|---------|---------|---------|---------|
| Number Accepted | 46 | 6 | | | |
| Number of Traditional submissions | 33 | 4 | | | |
| Number of Special submissions | 9 | 2 | | | |

| | | | | | |
|---|----|----|--|--|--|
| Number of Abbreviated submissions | 4 | 0 | | | |
| Average number of days to Accept / Refuse to Accept | 13 | 12 | | | |
| Number of Third Party submissions | 0 | 0 | | | |

Table 7.2 CBER - 510(k) Annual Shared Outcome Goal

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number Accepted | 46 | 6 | | | |
| Currently Under Review | 15 | 4 | | | |
| Number with Non-MDUFA Decision | 41 | 0 | | | |
| Number with MDUFA III Decision | 26 | 2 | | | |
| Percent of cohort closed | 67.4% | 33.3% | | | |
| Number with MDUFA III decision after trimming the upper and lower 2% | 16 | 0 | | | |
| Average Total Time to MDUFA III decision | 108 | 25 | | | |

Section 8 De Novo Petitions

Table 8.1 CBER – Annual General Metric Report for De Novo Classification Petitions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of De Novo Petitions Received | 2 | 0 | | | |
| Number of De Novo Petitions with Decision | 0 | 0 | | | |
| Number of De Novo Petitions with Decision Pending | 2 | 0 | | | |
| Average Number of Days to Decision | 0 | 0 | | | |

Section 9 Pre-Submissions

Section 9 Pre-Submission Center Level Metrics

Table 9.1 CBER – Pre-Submission Center Level Metrics

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of all qualified Pre-Submissions received | 45 | 9 | | | |
| Number requesting a meeting or teleconference | 35 | 5 | | | |
| Number with meetings or teleconferences granted | 32 | 5 | | | |
| Number with meeting granted and industry cancelled | 12 | 0 | | | |
| Number with meeting granted and FDA cancelled | 0 | 0 | | | |
| Number with meeting granted and pending within timeframe | 0 | 2 | | | |
| Number with meeting granted and pending outside timeframe | 3 | 1 | | | |
| Number with meetings or teleconferences held | 15 | 2 | | | |
| Average days to meeting | 68 | 92 | | | |
| 20th Percentile days to meeting | 55 | 0 | | | |
| 40th Percentile days to meeting | 58 | 0 | | | |
| 60th Percentile days to meeting | 61 | 91 | | | |
| 80th Percentile days to meeting | 70 | 91 | | | |
| Maximum days to meeting | 122 | 92 | | | |

BLAs**CBER – Annual General Metric Report for BLAs**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of Standard BLAs Filed | 9 | 0 | | | |
| Number of Standard BLA First Actions less than or equal to 10 months | 4 | 0 | | | |
| Number of Standard BLA First Actions greater than 10 months | 0 | 0 | | | |
| Number of Standard BLAs Pending | 5 | 0 | | | |
| Number of Priority BLA Filed | 0 | 0 | | | |
| Number of Priority BLA First Actions less than or equal to 10 months | 0 | 0 | | | |
| Number of Priority BLA First Actions greater than 10 months | 0 | 0 | | | |
| Number of Priority BLAs Pending | 0 | 0 | | | |

BLA Efficacy Supplements**CBER – Annual General Metric Report for BLA Efficacy Supplements**

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Standard Efficacy Supplements Filed | 0 | 0 | | | |
| Number of Standard Efficacy Supplements First Actions less than or equal to 10 months | 0 | 0 | | | |
| Number of Standard Efficacy Supplements First Actions greater than 10 months | 0 | 0 | | | |
| Number of Standard Efficacy Supplements Pending | 0 | 0 | | | |
| Number of Priority Efficacy Supplements Filed | 0 | 0 | | | |
| Number of Priority Efficacy Supplements First Actions less than or equal to 10 months | 0 | 0 | | | |

| | | | | | |
|--|---|---|--|--|--|
| Number of Priority Efficacy Supplements First Actions greater than 10 months | 0 | 0 | | | |
| Number of Priority Efficacy Supplements Pending | 0 | 0 | | | |

BLA Prior Approval Manufacturing Supplements
CBER – Annual General Metric Report for BLA PAS Supplements

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|--|---------|---------|---------|---------|---------|
| Number of Standard PAS Supplements Filed | 20 | 1 | | | |
| Number of Standard PAS Supplements First Actions less than or equal to 4months | 20 | 0 | | | |
| Number of Standard PAS Supplements First Actions greater than 4 months | 0 | 0 | | | |
| Number of Standard PAS Supplements Pending | 0 | 1 | | | |

BLA/BLA Resubmissions
CBER – Annual General Metric Report for BLA/BLA Resubmissions

| Performance Metric | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---------|---------|---------|---------|---------|
| Number of Class 1 Resubmissions Received | 10 | 0 | | | |
| Number of Class 1 Resubmission Actions less than or equal to 2 months | 10 | 0 | | | |
| Number of Standard Class 1 Resubmission First Actions greater than 2 months | 0 | 0 | | | |
| Number of Class 1 Resubmissions Pending | 0 | 0 | | | |
| Number of Class 2 Resubmissions Received | 0 | 1 | | | |
| Number of Class 2 Resubmission Actions less than or equal to 6 months | 0 | 0 | | | |
| Number of Class 2 Resubmission Actions greater than 6 months | 0 | 0 | | | |

| | | | | | |
|--|---|---|--|--|--|
| Number of Class 2 Resubmissions Pending | 0 | 1 | | | |
|--|---|---|--|--|--|

| FY 2014 Medical Device User Fee Collections as of December 31, 2013 ^{/1, 2} Excludes Unearned Fees | | | | | |
|---|---------------------|----------------|---------------------|----------------------|------------------------|
| | Receipts | Refunds | Net | Authorized | % of Authorized |
| Registration Fees | \$64,690,400 | \$0 | \$64,690,400 | | |
| Application Fees | \$11,702,571 | \$0 | \$11,702,571 | | |
| Total | \$76,392,971 | \$0 | \$76,392,971 | \$115,055,000 | 66% |

| Medical Device User Fee Collection History ^{/3} Excludes Unearned Fees, Includes Refunds | | | | | |
|---|----------------|----------------|----------------|----------------|----------------|
| MD I | FY 2003 | FY 2004 | FY 2005 | FY 2006 | FY 2007 |
| | \$21,620,549 | \$26,280,073 | \$31,814,416 | \$35,047,878 | \$28,723,939 |
| | | | | | |
| MD II | FY 2008 | FY 2009 | FY 2010 | FY 2011 | FY 2012 |
| | \$47,521,207 | \$55,790,145 | \$62,786,714 | \$69,586,954 | \$64,910,688 |
| | | | | | |
| MD III | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
| | \$98,208,765 | | | | |

Notes:

^{/1} Figures are based on Q1 data; subject to revision.

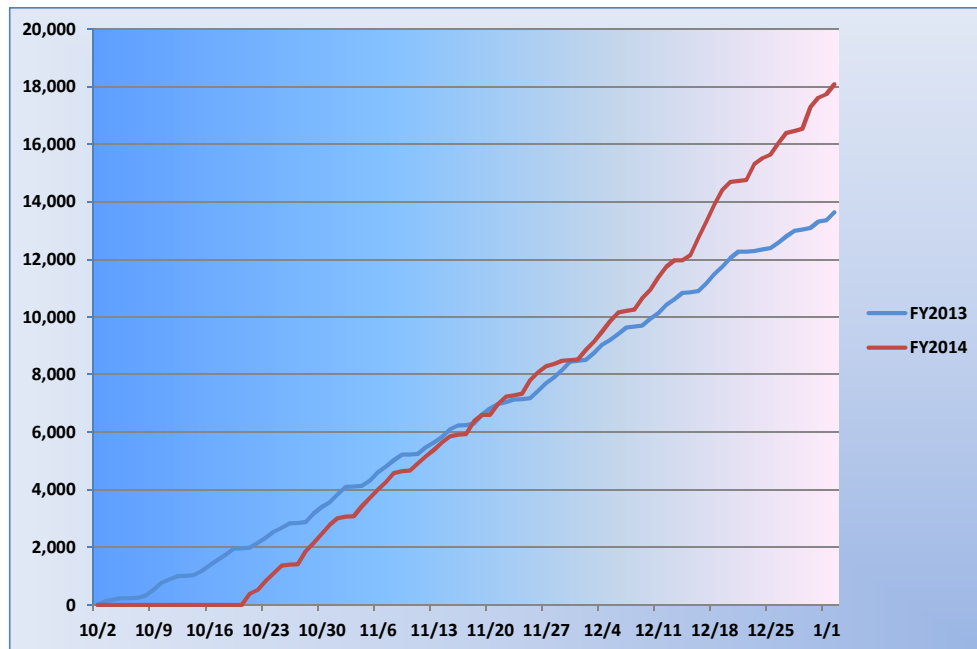
^{/2} Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2014.

^{/3} Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

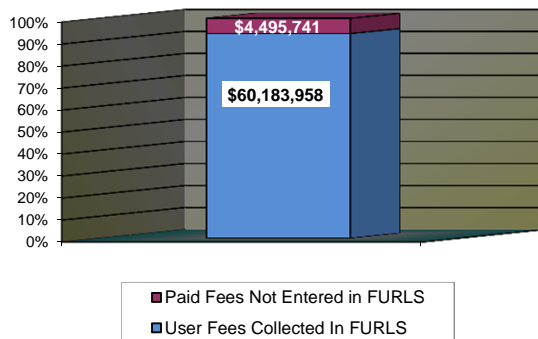
MDUFA III, Registrations, First Quarter Summary FY2014

| Registrations by Type | FY14 to Date (Currently Active) | | | FY2013 Year End Active Totals | | | Difference Thru 12/31/13 |
|--|---------------------------------|--------------|---------------|-------------------------------|---------------|---------------|-----------------------------|
| | Domestic | Foreign | Total | Domestic | Foreign | Total | |
| Est Type | | | | | | | |
| Manufacturer/ Complaint File Handler | 4,539 | 6,764 | 11,303 | 5,517 | 8,376 | 13,893 | -2,590 |
| Contract Manufacturer | 635 | 838 | 1,473 | 786 | 1,014 | 1,800 | -327 |
| Contract Sterilizer | 67 | 88 | 155 | 73 | 107 | 180 | -25 |
| Specification Developer | 1,232 | 297 | 1,529 | 1,661 | 363 | 2,024 | -495 |
| Reprocessor of Single Use Devices | 15 | 1 | 16 | 21 | 2 | 23 | -7 |
| U.S. Manufacturer of Export Only Devices | 105 | | 105 | 127 | | 127 | -22 |
| Repackager/Relabeler | 763 | 120 | 883 | 1,164 | 169 | 1,333 | -450 |
| Remanufacturer | 16 | 13 | 29 | 28 | 19 | 47 | -18 |
| Foreign Exporter/Private Label Distributor | 0 | 458 | 458 | 0 | 630 | 630 | -172 |
| Initial Importer | 2,185 | 0 | 2,185 | 3,272 | | 3,272 | -1,087 |
| Unknown | 6 | 7 | 13 | 15 | 8 | 23 | -10 |
| Total: | 9,563 | 8,586 | 18,149 | 12,664 | 10,688 | 23,352 | -5,203 |

Registration Progress - FY2013 Versus FY2014

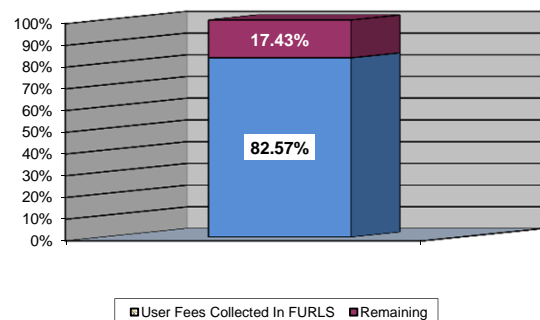


User Fees Collected Versus User Fees Paid



User Fee Progress

Goals - \$72,886,000 fees; 22,000 Registrations



MDUFA III Quarterly Performance Update

Independent Assessment of Medical Device Review Process

1st Quarter FY 2014 Status – January 29, 2014

Objectives

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications.

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications. Primary objectives include:

Phase 1:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket device reviews across FDA
- Development of implementation plans for selected recommendations
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results

Phase 2:

- Evaluation of the implementation of selected recommendations

Timeline

| Milestone | Planned | Status |
|--|---------------|-------------------------|
| FY 2013 | | |
| Publish Federal Register notice | December 2012 | Completed |
| Award contract | May 2013 | Completed June 2013 |
| Contract kickoff meeting between FDA and contractor | June 2013 | Completed July 2013 |
| Final workplan for Phase 1 | July 2013 | Completed August 2013 |
| Report on preliminary findings and high-priority recommendations | December 2013 | Completed December 2013 |
| FY 2014 | | |
| Implementation plan for high-priority recommendations | June 2014 | |
| Final report on complete findings and recommendations | June 2014 | |
| Implementation plan for final recommendations | December 2014 | |

| Milestone | Planned | Status |
|--|------------------|---------------|
| FY 2015 | | |
| Phase 2 kickoff meeting between FDA and contractor | April 2015 | |
| Final workplan for Phase 2 | May 2015 | |
| FY 2016 | | |
| Final evaluation report | February 1, 2016 | |

Progress to-date:

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1st Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013
- Finalized SOW based on feedback from Federal Register notice – March 25, 2013
- Issued request for proposal – April 19, 2013
- Awarded task order to Booz Allen Hamilton (BAH) – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – August 2, 2013
- Focus group with Medical Device Industry representatives – August 17, 2013
- Report on preliminary findings and high-priority recommendations – December 11, 2013
- BAH meeting with Medical Device Industry representatives – January 17, 2014

Planned Progress prior to 2nd Quarter Meeting FY 2014:

- Contractual progress reports and updates from BAH assessment team – Ongoing